
# SECURITY AND REGULATORY

# COMPLIANCE

# POLICY & PROCEDURES

# MANUAL

FOR DISTRIBUTION CENTERS

**Revised April 2004**

a.

# AMERISOURCEBERGEN SECURITY AND REGULATORY COMPLIANCE POLICY AND PROCEDURES MANUAL

## INDEX

# SECTION 1

# INTRODUCTION

## AmerisourceBergen Statement of Compliance

It is the intent of AmerisourceBergen to comply with all local, state, and federal laws and regulations applicable to this corporation and it's Distribution Centers (DC).

To accomplish this goal, all management and supervisory personnel at all levels of the corporation will constantly endeavor to ensure our operations are conducted in an ethical and honest manner in compliance with all applicable laws and regulations.

## A. GENERAL

Any product that creates safety and liability concerns for AmerisourceBergen may be considered a **dangerous drug**. The primary subcategories of dangerous drugs are as follows:

- **Prescription drugs** are any human drugs required by federal and state law or regulation to be dispensed only by a prescription. Prescription (Rx) products have strict sale and distribution regulations enforced by individual state licensing authorities. Each Distribution Center Manager (DCM) is responsible for knowing the laws and regulations of the states in which they distribute prescription drugs.

- **Controlled substances** are prescription drugs with strict production, sale, and distribution regulations enforced by the federal and state government. The Drug Enforcement Administration (DEA) categorizes these drugs into five Schedules, 1 - 5, according to their medicinal value and potential for abuse. Schedule 1 drugs have the highest potential for drug abuse and no known medicinal use. Schedule 5 drugs have the lowest potential for abuse. AmerisourceBergen only stocks Schedules 2-5.

- **Listed chemicals** include products containing ephedrine, pseudoephedrine, and phenylpropanolamine that may be used in the illicit production of methamphetamines. The DEA regulates the manufacture and distribution of Listed Chemicals.

To maintain familiarity with changing rules and regulations in the pharmaceutical industry that pertain to the storage and distribution of Controlled Substances, listed chemicals, and prescription product, each distribution center (DC) must have a current copy of the state regulations for the states in which they are licensed, as well as federal

regulations 21 CFR (Code of Federal Regulations Parts 200-299 and 1300 to End). In addition, each DC must maintain a current copy of this manual in order to maintain familiarity with corporate policies and procedures.

Each DC must maintain the appropriate state license(s) for all the states in which it is conducting business, when such license(s) are required by the state(s). Each DC must have all applicable state and federal licenses and permits posted and displayed within a display case or bulletin board near the main entrance of the building or a notice must be posted that states where the licenses and permits are maintained in file.

## B. TERMINOLOGY

**21 CFR regulations**: The requirements that must be continually met by a person or company registered with the Drug Enforcement Administration to possess or otherwise handle controlled substances and listed chemicals are contained in 21 CFR (Code of Federal Regulations) Part 1300 to end. Requirements for wholesale distributors of prescription drugs are contained in 21 CFR Part 200-299.

**ARCOS:** All schedule 2, 2N and 3 transactions are monitored by the DEA through a reporting system called ARCOS (Automation of Reports and Consolidated Order System). It is a violation of DEA regulations to disregard ARCOS procedures. Directions in the ARCOS section must be followed exactly as stated.

**Compliance Critical Associate:** An associate responsible for handling and/or recordkeeping of controlled substances, or in a related position which has an impact on the handling or recordkeeping of controlled substances. This position is assigned specific responsibility for ensuring continual and proper compliance with all corporate and government regulatory requirements.

**Compliance or Diversion Investigator:** An employee of the Drug Enforcement Administration authorized to inspect for compliance with 21 CFR regulations.

**Controlled Substances Act of 1970:** A Federal Act enacted to control certain specific controlled substances within legal channels.

**DEA Form 222 - Schedule 2 Order Form:** Order forms issued by the Drug Enforcement Administration (DEA) to registrants to record all transactions taking place with Schedule 2 Controlled Substances.

**Drug Enforcement Administration (DEA):** As part of the Department of Justice, this agency has been granted the authority and jurisdiction to inspect manufacturers, distributors, researchers, pharmacies, hospitals, practitioners, etc., who are registered with this agency to handle controlled substances for proper compliance

with Title 21 (21 CFR) regulations governing security and record keeping relating to controlled substances.

**Methamphetamine Control Act (MCA):** Became law in 1996 with the primary objective of minimizing the diversion of listed chemicals into illicit markets and illegal narcotic production. The resulting regulations of the MCA have subjected legitimate businesses to additional storage, reporting, and record-keeping requirements.

**Prescription Drug Marketing Act (PDMA):** An Federal Act, enacted in 1988, which requires state licensing of wholesale distributors of prescription drugs under Federal guidelines that include minimum standards for storage, handling, and recordkeeping.

**Registrant:** A person or company registered with the Drug Enforcement Administration to possess, distribute, sell, or otherwise handle controlled substances. All manufacturers, sellers, and purchasers of Controlled Substances are assigned a DEA registration number. The number registers and authorizes the business to legally process transactions of designated controlled substances.

**Recordkeeping:** All records and documents of the registrant, including invoices, purchase orders, credit memos, inventories, logs, files, computer printouts, etc., pertaining to the accurate and complete recording of all controlled substances transactions.

**Restricted Area:** Both the Schedule 2 vault and the Schedule 3-5 security cage(s), as well as the warehouse, receiving and shipping areas, are restricted areas and can only be entered by specifically authorized associates. Any entry or attempted entry other than authorized associates requires an escort. Presence of unauthorized associates in these areas will result in disciplinary action up to and including immediate termination.

**Schedule 2 Controlled Substances:** The most "potent" or highly abused controlled substances developed for legitimate use. A registered distributor must secure these items in a vault.

**Schedule 3, 4, 5 Controlled Substances:** Controlled substances of less "potency" but still under control by federal law. A registered distributor of these items must secure them in an approved security enclosure, usually a metal cage enclosure.

**Security measures:** All equipment and procedures utilized in meeting 21 CFR requirements as well as providing for the protection of all other assets of the corporation. This includes physical requirements and operational policy and procedures relating to the above.

## C. REQUIREMENT AND COMMITMENT TO ACCURACY

***21 CFR 1304.21(a)*** *Every registrant required to keep records pursuant to 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.*

The proper handling of all regulated product from the receipt of incoming orders through the filling, shipping, and delivery of the orders to our customers is our most critical production operation. **There is no margin for error** and associates who are making errors must be counseled with a written notation to file with possible disciplinary action up to an including termination.

We are subject to inspection by agents of the Drug Enforcement Administration (DEA) and state regulatory authorities at any time and our actual quantities on hand must balance with our sales, receipts, returns, and other transactions. For this reason, certain procedures must be followed precisely and uniformly. This manual will set forth these procedures and will be subject to periodic updating as necessary.

If for any reason a question should arise concerning handling or record keeping which is not answered in this manual, contact the Compliance Coordinator, Distribution Center Manager (DCM), or Corporate Security and Regulatory Affairs (CSRA) department for clarification.

The loss or inaccurate accountability of any controlled substance whether Schedule 2, 2N, 3, 3N, 4, or 5 could subject our company to violation of federal regulations which could result in a $10,000 fine per violation, costly legal action, and possibly the loss of our DEA registration and authorization to handle or distribute controlled substances. Therefore, the utmost care and concentration must be continually exercised in every process relating to controlled substances in our operation. This includes the filling and checking of controlled substance orders and the accurate recording of all controlled substance transactions.

## D. COMPLIANCE CRITICAL ASSOCIATES

A written job description must be present for each compliance critical position which assigns specific responsibility for ensuring continual and proper compliance with all corporate and government regulatory requirements and a dated copy of the job description must be present with the associate's signature to indicate that the job description has been reviewed with the associate and that the associate understands the requirements.

## E. GOVERNMENT CONTACTS

If DEA or any other regulatory agency is contacted for any reason, the date of the contact, name of the person contacted, brief record of the conversation, and the results of the contact must be documented on a **Government Contact Form, CSRA Form #2**. A copy of this form must be forwarded to CSRA.

## SECTION 2

## SECURITY CONTROLS

### A. GENERAL

The safety of associates is crucial, as is the protection of AmerisourceBergen assets. The procedures outlined in this chapter are minimum operating standards for achieving these ends.

**Note: The Corporate Security and Regulatory Affairs department provides training and guidance to all associates on robbery prevention, asset protection, and company policies regarding dishonesty and substance abuse**

***21 CFR 205.50(b)(1):*** *All facilities used for wholesale drug distribution shall be secure from unauthorized entry.*

***21 CFR 1301.71(a):*** *All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances*

***21 CFR 1301.71(b):*** *…In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following factors as he may deem relevant to the need for strict compliance with security requirements:*

*(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);*
*(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders);*
*(3) The quantity of controlled substances handled;*
*(4) The location of the premises and the relationship such location bears on security needs;*
*(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;*
*(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;*
*(7) The type of closures on vaults, safes, and secure enclosures;*
*(8) The adequacy of key control systems and/or combination lock systems;*
*(9) The adequacy of electric detection and alarm systems; if any including the use of supervised transmittal lines and standby power sources;*
*(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;*

*(11) The adequacy of supervision over employees having access to manufacturing and storage areas;*
*(12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;*
*(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;*
(14) *The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.*

It is required that the warehouse area be designated as a "Restricted Area" with only warehouse associates, or other associates who are specifically authorized in writing by management, allowed in the area. All others must be escorted by authorized personnel. Each entrance into the warehouse area shall be access controlled and shall be marked with a sign designating it as a "Restricted Area-Employee Escort Required."

All associates are prohibited from entering restricted areas without specific permission from management or supervision. These areas would include; the warehouse, shipping, receiving, controlled substance cage(s), and vault areas. Access to controlled substances is limited to an absolute minimum number of associates specifically authorized in writing by DC management.

The controlled substance cage and vault areas are designated as Restricted Areas with access permitted only to authorized associates. A listing of associates authorized access to the Schedule 2 vault area must be posted at the entrance of the vault and a listing of associates authorized access to the Schedule 3, 4, and 5 controlled substance cage must be posted at the entrance to the controlled substances cage.

**Note: Violation of the restricted area access policy or unauthorized entry into a restricted area is grounds for disciplinary action up to and including immediate termination.**

**B. KEY, COMBINATION, AND ACCESS CARD CONTROL**

Each DC must maintain a **written** and up-to-date log or record that lists each associate issued a key; a description of the location to which the key allows access; the date the key was issued; and, the associate issuing the key(s). The DC Manager must regulate key access to the DC by keeping a secured master set.

The Distribution Center's key/access card control program must include the following:

- A signed receipt for each issued key.
- An inventory list of all keys and access cards (spare and issued)
- A lock box for spare/un-issued keys and/or access cards

**Before** issuing keys or combinations to an associate, an updated criminal records check must be conducted through local law enforcement agencies and DEA. This records check must be returned and in file **before** issuance of the key or combination.

***21 CFR 1301.72(b)(ii)(a):*** *In the case of key locks, shall require key control which limits access to a limited number of employees, or;*

Keys to the cage areas and vault day gates must be stringently controlled by supervision, issued to the authorized associate prior to the shift, and returned to the supervisor at the end of the shift. A **Cage/Vault Key Log, CSRA Form #13** must be maintained to account for all keys signed in or out. Keys and combinations for these restricted areas will be issued **only** to an **absolute minimum** number of associates. Vault and cage keys must never leave the Distribution Center.

Associates are prohibited from loaning keys to the controlled substance cage or vault day gate without specific authorization from management, or from leaving keys unattended, or stored in desk drawers or other locations or in a manner which would leave them accessible to others. Supervisors must make a periodic check of the associate key(s) to see that the keys are in their possession.

***21 CFR 1301.72(b)(ii)(b):*** *In the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of employee having knowledge of the combination;*

Vault and cage locks and vault combinations must be changed whenever associates with keys, combinations, or access cards terminate employment or lose access to these areas.

Keys to forklifts and other industrial trucks must be placed in a locked box at the end of each shift or when not in use by an authorized associate.

Key and access-card losses and thefts must be reported to DC management no later than the next business day after discovery of the loss.

## C. PHYSICAL SECURITY

***21 CFR 205.50(a)(2):*** *All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space equipment and security conditions;*

***21 CFR 205.50(b)(1)(ii):*** *The outside perimeter of the premises shall be well lighted.*

**Exterior**

DCs must adhere to the following minimum exterior-security guidelines:

- Shrubbery must be a minimum of 12 inches below all windows.
- Trees that provide roof access must be trimmed or removed.
- The exterior building perimeter and all parking lots must be well lit.
- Regular operational checks of all exterior lighting should be accomplished to immediately disclose any inoperative units.
- Curtains must remain closed at night whether associates are in the building or not.
- The DC's street address should be clearly visible from the street both day and night.
- Display the street address on the roof if possible.
- Remove graffiti as soon as possible.
- Document and report any indications that the DC is used as an after-hours gathering spot by non-associates.
- Eliminate all markings that identify the building as a drug warehouse.
- Exterior hinges on all perimeter doors must be brazed or pinned.
- Perimeter doors that lead directly into the warehouse should have their exterior door handles removed and their locking mechanisms covered with strike plates at least eight inches in length.
- ALL perimeter doors (excluding emergency exits) leading from the warehouse directly outside which are used for pedestrian traffic (driver's door, etc.) must be kept closed and locked and equipped with a means (peephole, window, CCTV, etc.) by which to view the exterior entry point or the unlocked entrance door must be equipped with a "mantrap" or other restrictive barrier inside the door to prevent access beyond the immediate area of the door.
- The Alarm Company on a 24-hour basis must monitor all perimeter warehouse exit doors not utilized for pedestrian traffic.
- All ceiling vents/sky lights under 25 feet in height (or where roof access exists) must be connected to the DC's alarm system

**Interior**

DCs must adhere to the following minimum, interior-security guidelines:

- DCs should not allow direct access into their offices by visitors or non-associates.
- Lobbies should be equipped with a phone or other communication device to allow for communication without opening the interior lobby door. Where possible, glass partitions separating the office from the lobby should be of bullet-resistant construction with a teller-type pass-through tray (no straight pass-through openings).
- The interior lobby door should be equipped with a remotely operated electronic locking device and kept closed and locked at all times. The locking mechanisms of both the interior and exterior lobby doors should be protected by a heavy, metal

strike plate at least eight inches in length. All deadbolt locks should be of laminated steel construction and have at least a two-inch throw.
- Keep telephone and communication equipment rooms locked at all times, and practice strict key control.
- Make no reference to drugs in telephone directory listings. DC management must specifically request in writing that the telephone company or directory service not list the DC in the yellow pages.
- Equip all perimeter doors with panic bars and audible alarms to alert DC management of unauthorized openings. The doors must be of heavy, metal construction.
- All indoor areas of DCs are non-smoking environments.

**Lighting:**

- **Order Filling Areas**
  Lighting units will be provided in proper numbers and intensity to allow easy reading and accomplishment of the order filling and stocking requirements. (40-50 foot-candles recommended)

- **Back Stock Locations**
  Lighting units will be provided in proper numbers and intensity to allow easy reading and accomplishment of the order filling and stocking requirements. (20-25 foot-candles recommended)

**Data Processing**

Access to the Data Processing area is restricted to authorized associates only. Doors to the area must remain locked.

## D. ASSOCIATE SECURITY

- All associates must park their vehicles in designated associate parking areas.
- All associates must enter and exit the building through the same designated associate entrance.
- Time cards are to be utilized only by the associates to whom they are assigned.
- Personal packages, lunch boxes, bags, and outer garments are not allowed in the warehouse at any time. Signs prohibiting these items must be displayed on all doors leading from the office to the warehouse.
- A Package/Clothing Search Warning sign must be posted and visible to and from warehouse)
- Picking aprons are to remain in the warehouse at all times.
- Sales associates must be accompanied by management when in the warehouse.
- Report thefts, suspected thefts, or any suspicious activity to the DC Manager.

- Petty cash should be accessible only by authorized associates.
- Periodic refresher training courses should be provided to all associates regarding company policies for robbery prevention, thefts, drug use, and other security matters. The Corporate Security and Regulatory Affairs department provides assistance with this training.
- To safeguard against extortion attempts, the home telephone number of the DC Manager should remain unlisted.
- Use caution when giving out information over the phone regarding the nature of our business, the location of the DC, or the identity of DC management.
- Any suspicious inquiries must be reported to the Corporate Security and Regulatory Affairs department immediately.
- Associates must have knowledge of where panic buttons are located and how to use them.

## E. OPENING AND CLOSING THE DISTRIBUTION CENTER

**Note: The Distribution Center must only be opened and closed when a responsible exempt associate (supervision, management) is present.**

**To Open the Distribution Center with two or more associates**

1. No less than two associates, one in management, opens the DC.
2. Those opening the DC must meet at an off-site location and arrive at the DC together but in separate vehicles.
3. Before getting out of the vehicle, check the surroundings. In the event of anything suspicious, drive away and notify the police. Otherwise, one associate opens the DC while the other remains in his or her locked vehicle. The associate in the vehicle needs a clear view of the other as he or she opens the DC.
4. If a robbery attempt is made on one associate, the other is to leave and notify police.
5. After confirming that no one else is in the building, the associate in the DC signals to the associate in the vehicle, using a prearranged signal, that it is okay to enter.

**Note: An after-hours emergency Will Call constitutes an opening of the DC, and proper open and close procedures must be followed.**

**To Open the Distribution Center with less than two associates**

1. One associate (management/supervision) opens the DC.
2. Associate contacts Alarm Company via cellular telephone upon arrival at the DC.
3. Remain in constant contact as you unlock, enter, deactivate alarm system and re-lock DC from inside.

4. Once DC is secure, inform Alarm Company of expected duration of visit to DC.

**To Close the Distribution Center**

Follow the same procedures to close the DC as to open it.

## F. TRASH

- Never place trash containers near exterior doors including warehouse roll-up doors.
- Place trash containers outside the DC only when trash is to be picked up.
- Compact trash at the end of each day. If your DC does not have a compactor, the trash pickup service must compact it before leaving the premises.
- All outside trash containers must be kept locked at all times.
- Make periodic, unannounced inspections of trash compaction checking the trash ready for pickup, both inside and outside, to confirm that it has been properly compacted.
- All sensitive documents must be properly destroyed/shredded.

## G. VISITORS

Visitors should use the telephone or intercom in the lobby to identify themselves to office associates. All visitors should have a clearly stated, legitimate reason for requesting to enter the DC and should be able to provide positive identification (driver's license) and credentials when asked. Associates must request management assistance if they are unsure of a visitor's identity or if they feel at all uncomfortable with admitting a visitor into the DC.

Each DC must maintain a visitor log and a visitor badge program which lists the date, visitor's name, company, time of arrival and departure, and badge number issued. Visitors entering the reception area of an AmerisourceBergen DC must be restricted from entering the office area or other areas of the building by the locking of doors between the reception area and other parts of the building or though outer restrictive barrier techniques.

**Note: CSRA, Security Services can assist and issue the DCs sequentially numbered visitor badges upon request. Information maintained by CSRA will be the following: Division name and number, guest card number, date made, date sent, who made the request. Please direct your requests to Security Services, West Coast Management Center.**

***21 CFR 205.50(b)(1)(iii):*** *Entry into areas where prescription drugs are held shall be limited to authorized personnel.*

It is required that all visitors or non-warehouse associates desiring entry into the warehouse area be escorted by a warehouse or other authorized associate at all times they are present in the warehouse area. Associates who see an unescorted visitor in the DC, with or without a badge, should escort him or her back to the lobby and report the incident to their supervisor for proper documentation of the incident.

## H. CLEANING SERVICES

Contract cleaning service personnel must be supervised by DC management (or designee) while they are in the DC. Under no circumstances are contract cleaning personnel issued keys or pass cards. Management or a designated associate must closely inspect all cleaning materials and equipment removed from the DC by cleaning service personnel.

**Note: DC personnel must be present when trash is staged, transported and placed in the external trash receptacles.**

All contracted cleaning services must possess general liability and third-party insurance policies providing insurance coverage to AmerisourceBergen Corporation. A photocopy of the cleaning service's proof of insurance must be kept on file in the DC.

## I. ASSOCIATE PURCHASES

If permitted by DC Management, associates may purchase any non-prescription product, with the exception of listed chemical products, so long as it is not outdated. Purchase procedures are as follows:

1. Create a Work Order.
2. Associates are not permitted to fill their own orders.
3. Before the product is removed from the DC, management verifies that the product matches the invoice, then signs and dates the invoice.
4. Payment is by COD or payroll deduction only.
5. The DC must maintain a separate purchase file for associate purchases.

## J. PRODUCT

Under no circumstances is product to leave any DC without an invoice. The only exceptions are:

- **Exchange product.** An Exchange Form, signed by management, must accompany product to a customer to rectify an incorrect transaction.
- **Manufacturer's non-Rx samples.** Product samples received from supplier representatives must be stored in the front office. The DC Manager and/or Compliance Coordinator are responsible for reviewing the product prior to its

leaving the building. No associates are permitted to accept any manufacturer's prescription drug samples from any source.

- **Product being destroyed.** Supplier-credited product may not be purchased by any associates or outside salvage companies. If management wishes to donate it to a local charity, they can do so with the supplier's permission.
- **Computer-caused problems.** Only the DC Manager or his/her designee may deliver customer orders to a customer without computer-generated invoices or price stickers.

## K. DURESS CODES

Management, supervision, cage and vault associates must be trained in the use of Duress codes and what to do in a Duress situation utilizing the AmerisourceBergen **Duress Code Instruction, CSRA Form #28.**

## L. ROBBERY PREVENTION

AmerisourceBergen's **Violence Prevention Procedures, CSRA Form #30(a)** must be posted so that associates become familiar with proper procedures. Receptionists and customer service representatives must be aware of proper procedures when receiving an obscene, harassing phone call or bomb threat.
Periodic refresher training should be provided to all associates regarding company policies for robbery prevention, thefts, and other security matters utilizing the AmerisourceBergen **Robbery & Violence Prevention Form, CSRA Form #29**.
Contact the CSRA department for assistance.

## M. ALARM SYSTEMS

All DCs are equipped with exterior and interior intrusion and fire-detection systems in accordance with Federal, state, and local regulations.

### Alarm Testing

An operational test must be conducted of the entire burglar alarm system, including the vault alarm system, at least **quarterly** by and in the presence of only associates with authorized access to the alarm system or by alarm company personnel.

All alarm tests must be conducted as follows:
"Walk test" the system opening doors, activating holdup alarms and motion sensors.
If the system is equipped with a transponder, verify that the alarm trips on the board.
Call the alarm company and confirm that the alarm signal is duly transmitted.

The **quarterly** burglar alarm system test report must be completed and a copy forwarded to the CSRA Department no later than the 15th of the following month.

The DC manager must review alarm activity reports from the Alarm Company on a regular basis and must create and keep up to date the following lists and supply them to the alarm company:

1. Associates authorized to open or close each alarm system.
2. Associates on the after hours Call-up List, in calling order.

**Alarm Activations**

All alarm activations, including false alarms, must be reported to the CSRA department no later than the next business day. Report alarm activations in the following manner:

1. The associate reporting the alarm activation must complete the **Report of Alarm Activation, CSRA Form #9.**
2. Fax the completed form to the CSRA department no later than the next business day.
3. Keep a copy of the form on file in the DC.

If you are on the Call-Up List and notified of alarm activation, call the alarm company back and verify:

1. Whether the call was legitimate.
2. The reason for the alarm.
3. The time and date of the alarm.
4. The system (warehouse, office, or vault), zone, and type (motion, contact, panic) of alarm.
5. The nature of alarm company response.
6. The names of the associates responding to the alarm.
7. Whether the police were dispatched and when.
8. The name of the local police department.
9. Estimated Time of Arrival (ETA) at DC by responding associate.

Upon arrival at the DC:

1. From off site, observe the exterior premises from your locked vehicle. Circle the DC in your vehicle if possible. If police have not arrived, remain in your locked vehicle.
2. If the police do not arrive shortly, call the alarm company and have them dispatch the police again.
3. After the police check the exterior, open the front door.
4. Do not enter the DC without police presence.

If there is evidence of entry:

1. Touch nothing.
2. Do not leave the premises until the point of entry is repaired, and the alarm system is operational.
3. Notify the CSRA department no later than the next business day.

If no evidence of entry is found:

1. Remain at the DC until the alarm system is reset.
2. Request that an alarm technician repair the alarm system if necessary.
3. Notify the CSRA department no later then the next business day.

Associates working in the cage and vault areas are not to place or otherwise store product in a manner that will "block" or otherwise obstruct the alarm equipment rendering it ineffective.

It is required that the vault alarm system be separate from other building alarm systems and that the transmission line to the receiving station be protected with a Grade AA High Line Security device, cellular or other DEA-approved equipment.

## N. PHYSICAL SECURITY CONTROLS (VAULT)

***21 CFR 1301.72(a)(3):*** *A vault constructed after September 1, 1971:*

a. *The walls, floors and ceiling of which vault are constructed of at least 8 inches of reinforced concrete, or other substantial masonry, reinforced vertically or horizontally with ½ inch steel rods tied 6 inches on center, or structural equivalent to such reinforced walls, floors, and ceilings;*

b. *The door and frame unit of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry; 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;*

c. *Which vault, if operations require it to remain open for frequent access, is equipped with a "day gate" which is self-closing, self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;*

d. *The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the*

*Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;*

e. *The door of which vault is equipped with contact switches; and*

f. *Which vault has one of the following; Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.*

All narcotic vaults constructed after September 1, 1971, must meet physical security standards as outlined in 21 Code of Federal Regulations, Part 1301.72(a)(3).

Any anticipated or proposed vault construction or expansion must be submitted to Corporate Security and Regulatory Affairs Department for review of 21 CFR specifications and requirements and approval.

One or more of the following must be available at the DC to document the construction of the vault: (a) blueprints in file which indicates the required construction specifications, (b) photographs taken during construction of the vault indicating compliance with the construction specifications, or (c) a notarized letter from the contractor stating the vault was constructed to all required specifications.

All vaults must be equipped with a day gate constructed of at least 10 gauge steel metal mesh and mounted in/on a metal door frame. Vault associates must check that the day gate is securely closed and locked each time they enter or depart the vault.

Vault day gate locks must be protected by reinforced plates to prevent unauthorized access by defeat or manipulation of the door latch or lock.

Self-closing, self-locking capability of the day gate(s) must be continually maintained in operable condition, and the day gate(s) must not be blocked open or otherwise overridden.

A refrigerator must be located inside the Schedule 2 vault for the storage of Schedule 2 and 2N items requiring refrigeration. No Schedule 2 or 2N controlled substances are permitted to be stored in refrigerators located outside the vault without written approval from DEA.

***21 CFR 1301.72(d): Accessibility to storage areas.*** *The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.*

An updated **Authorized Access Listing, CSRA Form #11(a)** of associates authorized by management to enter the controlled substances vault must be signed by the DCM and posted at each entrance to the vault. A **"Restricted Area – Authorized Personnel Only"** sign, **CSRA Form #11(b)** must be posted at each entrance to the controlled substance vault.

**All non-authorized persons requiring access to a restricted vault area must be escorted and observed at all times they are present in the restricted area.**

All work activity involving the double-checking of receipts, filling, packing, and other requirements relating to Schedule 2 product and transactions must be conducted totally within the vault area and not outside this restricted area.

## O. PHYSICAL SECURITY CONTROLS (CAGE)

***21 CFR 1301.72(b)(4):*** *A cage, located within a building on the premises, meeting the following specifications:*

- *(i) Having walls constructed of not less than No.10 gauge steel fabric mounted on steel posts, which posts are:*
  - a. *At least one inch in diameter;*
  - b. *Set in concrete or installed with lag bolts that are pinned or brazed; and*
  - c. *Which are placed no more than ten feet apart with horizontal one and one-half inch reinforcements every sixty inches;*
- *(ii) Having a mesh construction with openings of not more than two and one half inches across the square;*
- *(iii) Having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height,*
- *(iv) Is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all the requirements of 21 CFR 1301.72(b)(3)(ii), and*
- (v) *Is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency, or a local or State police agency, each having a legal duty to respond, or a 24-hour control station operated by the registrant, or such other source of protection as the Administrator may approve.*

All controlled substance cages must meet physical security standards as outlined in 21 Code of Federal Regulations, Part 1301.72(b)(4).

Any anticipated or proposed cage construction or expansion must be submitted to Corporate Security and Regulatory Affairs Department for review of 21 CFR specifications and requirements and approval.

Cage associates must check that the doors of the cage are securely closed and locked each time they enter or depart the cage.

Cage door locks must be protected by reinforced plates to prevent unauthorized access by defeat or manipulation of the door latch or lock.

All attaching bolts on the locking hardware must have flanged heads to prevent removal or be brazed if mounted on the exterior of the locking plate or device.

No static shelving will be located immediately adjacent to the perimeter walls of the cages nor will small containers of controlled substances be present on shelving immediately adjacent to the perimeter walls of the cage, unless the interior of the wall is covered with substantial strength wire mesh containing smaller openings than two and one-half inches across the square.

The walls of the cage must be bolted directly to the floor with no openings between the floor and wall panel, and wall panels containing "sweep space" between the wall and floor be closed by the installation of 10 gauge metal filler panels securely fastened to the floor, bottom of the wall panel, and to the upright supports of the wall panels.

Self-closing, self-locking capability of cage gate(s) must be continually maintained in operable condition, and the cage gate(s) must not be blocked open or otherwise overridden.

A refrigerator must be located inside the controlled substance cage for the storage of Schedule 3-5 items requiring refrigeration. No Schedule 3-5 controlled substances are permitted to be stored in refrigerators located outside the controlled substance cage without written approval from DEA.

***21 CFR 1301.72(d): Accessibility to storage areas.*** *The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.*

An updated **Authorized Access Listing, CSRA Form #11(a)** of associates authorized by management to enter the controlled substances cage must be signed by the DCM and posted at each entrance to the cage. A **"Restricted Area – Authorized Personnel**

**Only"** sign, **CSRA Form #11(b)** must be posted at each entrance to the controlled substance cage.

**All non-authorized persons requiring access to a restricted cage area must be escorted and observed at all times they are present in the restricted area.**

**Storage of Non-Controlled Product in the Controlled Substance Cage**

***21 CFR 1301.72(b)(8)(ii):*** *Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by 21 CFR 1301.72(b), provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the Special Agent in Charge of DEA for the area in which such storage area is situated.*

Before storing any non-controlled product—including state-designated Controlled Substance products—in the Controlled Substance cage, DCs must do the following:

- Request permission from the local DEA via written letter (sent certified mail) which specifically identifies non-controlled product to be stored in the Controlled Substance cage
- Obtain, in writing, the DEA's permission to store the identified products in the controlled substance cage
- Post the DEA's letter of permission in the controlled substance cage or have the letter readily retrievable

Listed chemicals should be stored in a central location of the warehouse. If the DC's current storage of the listed chemical product does not provide adequate security against theft or diversion, the DC may have to increase the security by either relocating targeted listed chemical product to the controlled substance cage or constructing a controlled access area to store listed chemical product.

## P. VEHICLE SECURITY

See **"Delivery Policies & Procedures", CSRA Form #26**.

## Q. LOCKER POLICY

See "AmerisourceBergen **Associate Locker Policy", CSRA Form #38** which includes the "Associate Locker Agreement"

## R. WEAPONS POLICY

Possession of firearms, other weapons or explosives on company property, in company vehicles or in a personal vehicle on company property is prohibited.

## S. SECURITY INSPECTIONS POLICY

AmerisourceBergen wishes to maintain a work environment that is free of illegal drugs, alcohol, firearms, explosives or other improper materials. To this end, the Company prohibits the control, possession, transfer, sale or use of such materials on its premises, including in its vehicles. The cooperation of all associates is required in the administration of this policy.

For further information on ABC's Security Inspections Policy and Procedures refer to Policy no. HR-6.4 in the AmerisourceBergen Associate Handbook.

## T. WORKPLACE VIOLENCE POLICY

It is the policy of AmerisourceBergen that it will not tolerate any form of violence in the workplace. It is the responsibility of all associates to immediately report any incidents of violence. If an associate violates this policy in any manner, the associate shall be subject to disciplinary action, up to and including immediate termination.

For further information on ABC's Workplace Violence Policy and Procedures refer to Policy no. HR 1.2 in the AmerisourceBergen associate handbook

## SECTION 3

## RECEIVING PROCEDURES

### A. RECEIVING DOCK SECURITY

Receiving dock areas are "Restricted Areas" and "Off limits" to all but department associates and only company associates requiring access to the area in performance of their normal job duties. Smoke, coffee, lunch or any other type breaks are prohibited in the receiving area. The company provides a break room for this purpose.

Shipping and receiving areas must be physically separated if possible. If necessary, install a permanent barrier such as chain link fencing between the two areas.

Receiving dock doors are to remain closed and incapable of being opened from the outside, except when trucks are entering or leaving the dock area, or are in the process of being loaded or unloaded and such activity prevents the doors from being closed.

Doors required to be opened for ventilation or other reasons must be equipped with expandable metal gates (scissor gates) or grating properly installed to prevent unauthorized access to the dock area.

Sufficient barriers or procedures must be present at the receiving dock which prevents commercial drivers or other persons from entering the warehouse area or areas of the building other than the receiving dock.

All non-associates, including contract and common carrier drivers, must be accompanied by an associate when walking through the warehouse or office areas.

Associates' personal vehicles must be parked more than 50 feet away from the shipping and receiving docks in designated associate parking areas.

Piece counts must be conducted on all inbound deliveries prior to signing a receipt acknowledgement on the carrier's manifest.

If incoming shipments of controlled substances are not immediately transported to the controlled substance cage or vault after being checked in, the items must be maintained under **constant supervision** until the first opportunity to transport them to the security area arises.

Receipt documents used in the receiving department to check in the incoming controlled substances must be taken to the cage or vault clerk, as applicable, so that receipt quantities can be verified at the time the product is checked into the cage or

vault. After verifying all receipt quantities as being correct, the cage or vault clerk must initial and date the receiving document.

Controlled substance receipts must be checked in at receiving, verified at the cage or vault, and entered into the computer system **on the same date they are actually received** in accordance with 21 CFR 1304.21(d).

Any unchecked freight remaining in the receiving area must be checked for the presence of controlled substances by printing the PO/Receivers and/or checking the packing list for each shipment. Under no circumstances will controlled substances be left unsupervised in the receiving area.

**B. SCHEDULE 2 CONTROLLED SUBSTANCES**

Each book of Schedule 2 order forms must be reviewed upon receipt by the company to verify that all sequentially numbered order forms issued by DEA are, in fact, present.

Schedule 2 order forms used for the purchase of controlled substances by the DC, or by the DC's authorized representative, must be maintained in a secure location at the DC.

Schedule 2 Controlled Substances are ordered from the manufacturer on a Purchase Order from our company that contains only Schedule 2 items. Blue copies (Copy 3) of the Schedule 2 DEA 222 order forms are maintained on file in the Schedule 2 vault.

Schedule 2 Controlled Substances are not to be purchased from Non-Manufacturer Vendors without written authorization from CSRA.

**All incoming orders containing Schedule 2 product must receive priority attention** and the following accomplished:

Upon receipt of a shipment from a manufacturer, the purchase order number must be checked against the computer file on the computer system terminal located in the Receiving Department.

The entire incoming order must be checked by comparing the vendor's packing list against the purchase order/receiver and actual items received. The receiving clerk must initial and date the receiving documentation.

Schedule 2 controlled substances must be taken immediately to the vault or maintained under constant supervision while outside the vault.

The entire incoming order is double checked by the vault clerk by comparing the vendor's packing list against the purchase order or receiver and actual items received.

The vault clerk must also initial and date the receiving documentation.

***21 CFR 1305.09(e):*** *The purchaser shall record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.*

The NDC number must be recorded on Copy 3 (blue copy) of DEA Form 222 on each item received as well as the quantity and date received. Careful attention must be given to NDC number of each item received to ensure computer information is correct.

If product is damaged, leaking, or broken, report this fact to a supervisor immediately. Damaged Schedule 2 substances must be received and taken to the vault.

**Note: If a discrepancy is found when checking in a Schedule 2 controlled substance purchase order and a back-order situation is not indicated, contact an authorized associate (DCM, Compliance Coordinator, Inventory Manager, etc.). Call the manufacturer to report the discrepancy, and immediately check the boxes for tampering.**

The incomplete DEA Form 222 is maintained in the manufacturer's open order file to await receipt of the back-ordered item(s). This procedure must be repeated until the order form is completely received or until the order is canceled in the event the manufacturer does not back order product or the sixty-day limit is met.

***21 CFR 1305.13[c]:*** *Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of 2 years. If a purchaser has several registered locations, he/she must retain Copy 3 of the executed order forms or any attached statement or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to 1305.06(d)) at the registered location printed on the order form.*

Completed Copy 3 (blue copy) of DEA Form 222 must not be attached to POs or other records and must be maintained separately from all other records of the DC. Copies of purchase orders or receivers and packing lists must also be maintained separately in the compliance files at the DC.

All Schedule 2 controlled substances must be constantly monitored during the receiving process and during all transfers. At no time will controlled substances be left unattended or unsupervised. It is strictly against company policy for any controlled substances to be left unattended outside the vault area. Violation of this policy is cause for disciplinary action up to and including termination.

**C. SCHEDULE 3, 3N, 4, 5 CONTROLLED SUBSTANCES**

Schedule 3-5 controlled substances are ordered from the manufacturer on a purchase order from our company that only contains Schedule 3-5 items. A copy of these purchase orders is maintained in the computer system. Upon receipt of a shipment from a manufacturer, the purchase order number must be checked against the computer file on the computer system terminal located in the Receiving Department.

**All incoming orders containing Schedule 3 - 5 product must receive priority attention** and the following accomplished:

The entire incoming order is checked by comparing the vendor packing list against the purchase order or receiver and actual items received. The receiving clerk must initial and date the receiving documentation.

Schedule 3 - 5 controlled substances must be immediately taken to the cage or maintained under constant supervision while outside the cage.

The entire incoming order is double checked by the cage clerk by comparing the vendor's packing list against the purchase order or receiver and actual items received. The cage clerk must also initial and date the receiving documentation.

Damaged Schedule 3-5 items must be received and forwarded to the cage. The cage associate must double check the product against the Receiver. If the product is damaged, leaking, or broken, report this fact to a supervisor immediately.

**Note: If a discrepancy is found when checking in a Schedule 3 - 5 controlled substance purchase order and a back-order situation is not indicated, contact an authorized associate (DCM, Compliance Coordinator, Inventory Manager, etc.). Call the manufacturer to report the discrepancy, and immediately check the boxes for tampering.**

Copies of the receiving documents for the Schedule 3-5 purchases must be maintained separately or in a readily retrievable manner at the DC.

The need for total and complete accuracy in the handling of Schedule 3-5 controlled substances is equally as important and necessary as the handling of Schedule 2 items.

All Schedule 3-5 controlled substances receipts must be monitored constantly during the receiving process and during all transfers. At no time will controlled substances be left unattended or unsupervised. It is strictly against company policy for any controlled substances to be left unattended outside the cage area. Violation of this policy is cause for disciplinary action up to and including termination.

**NOTE: ALL CONTROLLED SUBSTANCES MUST BE RECEIPTED AND STORED IN THE VAULT OR CAGE ON THE DATE ACTUALLY RECEIVED.**

## D. PRESCRIPTION DRUGS

**All incoming shipments of prescription drug products will be examined visually by Receiving Clerks for proper identity and to prevent the acceptance of prescription drugs that are damaged, contaminated or otherwise unfit or potentially unfit for distribution.**

## E. NON-MANUFACTURING VENDORS (NMVs)

**1.**

**Note:** All purchases from NMVs must be conducted with NMVs that have been investigated and approved in accordance with the ABC Corporate Compliance Program. Each purchase must be made from an Authorized Distributor (AD) of record for the product manufacturer or is accompanied by a product "Pedigree" that meets all requirements as outlined in the Prescription Drug Marketing Act (PDMA).

Each receiving facility shall annually train all employees responsible for receiving products from approved NMVs. All shipments must be cleared through these associates whose responsibilities shall include determining that all products are in compliance with the Company's policies.

Examine all goods form approved NMVs to determine whether:

a. all products have an effective expiration date more than 12 months following the date of receipt;
b. there is any evidence that the products have been opened, altered or improperly stored, handled or transported; and
a. there is any evidence that the products were previously sold to or sold by any entity not licensed as a prescription drug manufacturer or wholesaler, i.e. shrink-wrapped product with the expiration date only exposed for one of the bottles, price stickers on the bottles, prescription labels on product, etc.

Do not accept:

1. products with an effective expiration date less than 12 months from the date of receipt;
2. products that are not:
    a. "standard American trade;" and
    b. in current "consumer packaging;"
3. any products with foreign labeling;
4. any products subject to any lawful resale restriction imposed by the manufacturer;

5. any products that any associate knows or has reason to believe was previously sold to or sold by an entity not licensed as a prescription drug manufacturer or wholesaler;
6. any products that appear to have been opened, altered or improperly stored, handled or transported;
7. quantities over the order quantity; or
8. products not in tamper resistant packages.

The associate receiving the shipment must sign the acknowledgement that automatically prints on the PO receiver.

## SECTION 4

## INTER-COMPANY TRANSFER OF CONTROLLED SUBSTANCES

### A. GENERAL

Controlled substances are occasionally transferred from one AmerisourceBergen DC to other AmerisourceBergen DCs.

### B. INTER-COMPANY TRANSFERS

The sale of controlled substances to other AmerisourceBergen DCs requires that DC be set up as a customer in our computer system.

Any Schedule 2 sale made to another AmerisourceBergen DC requires the presence of a DEA Form 222 and preparation of a **work order** as in any other Schedule 2 sale.

Any Schedule 3-5 sale made to another AmerisourceBergen DC requires the preparation of a **work order** as in any other Schedule 3-5 sale.

## SECTION 5

## FILLING ORDERS

### A. GENERAL

No prescription drug product will be removed from the shelf location for shipment or transfer within the building without first examining the item to ensure the item is within the expiration date, and that it has not sustained damage. The condition of prescription drug products will be checked prior to placement of the items on the stock shelves to ensure the product has not been damaged, adulterated, or is out-of-date.

Each outgoing shipment of prescription drugs is to be inspected carefully at time of filling for the identity of the drugs, to determine that the product is within the expiration date, and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

**Schedule 2 controlled substances:**

No Schedule 2 product will be shipped unless a computer generated **work order** and Schedule 2 order form (DEA 222) are present for the order. Either or both documents may be waived for later preparation or receipt only **after having obtained approval from DEA** having jurisdiction over the DC.

***21 CFR 1309 Procedure for filling order forms.***

*(a) The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier, and retain Copy 3 in his own files.*

*(b) The supplier shall fill the order, if possible and if he/she desires to do so, and record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid for more than 60 days after its execution by the purchaser…*

*(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the Administration on the order form…*

*(d) The supplier shall retain Copy 1 of the order form for his/her own files and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 shall be forwarded at the close of the*

*month during which the order is filled; if an order is filled by partial shipments, Copy 2 shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.*

Schedule 2 controlled substance orders are received into our DCs on a DEA Form 222 from the customer. We must receive two copies of this form, the original (brown copy 1) and the first carbon (green copy 2). Schedule 2 order forms must be prepared by use of a typewriter, pen, or indelible pencil only.

Upon completion, the original must remain in our files for a period of three (3) years; the green copy must be sent to the DEA office, via traceable means, having jurisdiction over our DC within fifteen days of the end of each calendar month's transactions.

**Schedule 3, 4, 5 controlled substances:**

**No Schedule 3, 4, 5 controlled substances will be shipped unless a computer generated work order is present.**

**B. EXCESSIVE/SUSPICIOUS ORDERS OF CONTROLLED SUBSTANCES**

***21 CFR 1301.74(b):*** *The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall infor the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.*

A **suspicious order** is any order that is of unusual size or frequency or that deviates substantially from the normal pattern. The Compliance Coordinator is responsible for ensuring that all associates are thoroughly familiar with the procedures for recognizing and reporting such orders.

The DCM and/or Compliance Coordinator must have thorough knowledge of and be able to articulate how, when and where their DC is reporting suspicious orders to DEA.

**For DCs on the "Distrack" system:**

**Suspicious Order Monitoring – Base Levels, CSRA Form #18** must be present and posted in both the cage and vault areas. These procedures contain "base trigger levels" over which the order clerks must contact a supervisor or other management official for determination of how to handle the order. Procedures must indicate the process for notifying DEA whether the order is filled, reduced or refused. Copies of any suspicious order documents (Schedule 2 order forms and/or work orders) must be

maintained in file for a period of three years, with a copy of the registered delivery receipt attached to the applicable documents(s) that proves delivery to DEA.

In addition to the above, the HDMA computerized Suspicious Order Monitoring (SOM) Program will be in place at each DC and will be forwarded to DEA in a manner that provides the company with a delivery receipt. Or a review of printouts of **all** controlled substances sales taking place for the month will be reviewed by management or supervision, suspicious orders highlighted, and the printout forwarded to DEA in a manner that provides the company with a delivery receipt. This delivery receipt must be attached to the copy of the printout maintained in company file.
The printout must be forwarded to DEA within 15 days after the close of the month's controlled substances sales.

**For DCs on the "Star" System:**

Reporting of suspicious orders is automated to report suspicious or unusual transactions to the DEA electronically on a daily basis. The DCM or Compliance Coordinator must review, sign and date this report on a daily basis. On a quarterly basis, contact your local DEA office to ensure they are receiving daily reports.

**Listed Chemicals**

Each DC must report suspicious orders and/or unusual transactions involving listed chemicals to their local DEA office. Suspicious orders include transactions involving "extraordinary quantities," transactions involving an uncommon method of payment or delivery, and any other types of sales that would indicate that the purchased product might be used to manufacture illicit substances.

This notification should be by telephone and then followed with a written report within 15 days of notification. A **Regulated Chemical Transaction Report, CSRA Form #21** must be used for this notification.

## C. SCHEDULE 2 CONTROLLED SUBSTANCES

**Submission of Schedule 2 Order Forms By Customers:**
Schedule 2 order forms (DEA Form 222) completed by customers are to be mailed to the DC or returned via the AmerisourceBergen or contract/common carrier driver only within a sealed envelope. The courier service must deliver the order forms **directly** to the DC without delay and as quickly as possible.

Upon arrival at the facility, Schedule 2 Order Forms must be reviewed by a Controlled Substance Vault Clerk, Order Entry Clerk and/or the Compliance Coordinator. Controlled Substance Clerks in the vault must be responsible for final review of order forms before filling order.

**DEA Order Form Guidelines**, **CSRA Form #32** must be posted in the vault for reference by Schedule 2 Order Clerks. The presence of HDMA's **"Form 222 Survival Guide"** in the vault will satisfy this requirement provided it is visible and readily accessible to Schedule 2 order clerks.

**Schedule 2 Order Entry:** Each Schedule 2 order form (DEA Form 222) received must be entered into the computer to produce a work order.

***21 CFR 1305.06 Procedure for executing order forms***

*(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.*

*(b) Only one item shall be entered on each numbered line…The number of lines completed shall be noted on that form at the bottom of the form, in the space provided.*

*(c) The name ands address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any form.*

*(d) Each order form shall be signed and dated by a person authorized to sign an application for registration. The name of the purchaser, if different from the individual signing the order form, shall be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the order form, provided that all unexecuted order forms are delivered promptly to the registered location…*

**NO SCHEDULE 2 ORDER CAN BE PROCESSED WITHOUT A WORK ORDER BEING PROPERLY PREPARED.**

**NO SCHEDULE 2 PRODUCT WILL LEAVE THE VAULT FOR ANY REASON UNTIL A DEA FORM 222 IS IN OUR POSSESSION.**

**Reviewing Schedule 2 Order Forms:**

The first and perhaps most important function the Schedule 2 Order Clerk(s) must perform is to determine that:

(1) Order forms are prepared by use of a typewriter, pen, or indelible pencil only.

(2) The customer's DEA registration number printed on the work order is identical to that printed on the DEA Form 222,

(3) The number of the DEA Form 222 is correctly printed on the work order,

(4) That the customer has "schedule authorization" on the order form to purchase the items they are ordering.

(5) That no changes/alterations have been made on the DEA Form 222 involving quantity, size, or strength of any item ordered on the form.

(6) That the order form is signed.

**UNSIGNED ORDER FORMS CANNOT BE FILLED AND MUST BE RETURNED TO THE CUSTOMER FOR SIGNING**

(7) The "Number of Lines Ordered" block is filled in and matches the number of lines ordered.

(8) That all other portions of the order form are completed and correct.

***21 CFR 1305.11 Unaccepted and defective order forms***

*(e) No order form shall be filled if it:*

*1. Is not complete, legible, or properly prepared, executed, or endorsed; or*

*2. Shows any alteration, erasure, or change of any description.*

*(f) If an order form cannot be filled for any reason under this section, the supplier shall return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for the purposes of this paragraph.*

*(g) When received by the purchaser, Copies 1 and 2 of the order form and the statement shall be attached to Copy 3 and retained in the files of the purchaser in accordance with 1305.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.*

***21 CFR 1305.15 Cancellation and voiding of order forms***

*(a) A purchaser may cancel part or all of an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for number of items shipped.*

*(b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in paragraph (a) of this section.*

**When a customer has incorrectly filled out DEA Form 222:**
If a line on a DEA Form 222 contains an alteration, mistake, or is incomplete, that line can be cancelled and the rest of the remaining lines filled. Alterations or mistakes in areas other than the line items require complete cancellation. The DC must indicate the cancellation on Copies 1 and 2 of the order form by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

The DC must notify the customer in writing, via packing list, invoice, **Notification of Inability to Fill Schedule 2 Order, CSRA Form #33** etc., the reason the line in question cannot be filled. A copy of the **CSRA Form #33** must be forwarded to the customer with a copy maintained in file for three years. If possible, call the customer to inform them why the line cannot be filled, so that the customer can execute a new DEA Form 222 the same day.

If a customer incorrectly enters an item on a DEA Form 222, this particular item cannot be filled. However, the entire order need not be cancelled. Cancel only the specific line item on the order form and notify the customer, in writing, by sending them a DEA Form 222 Return Form explaining why that line item was cancelled.

When any defective Schedule 2 order form is return to a customer, the defective order form and the form letter or statement explaining the reason for return must be copied an retained in the company file for a period of three years.

**Filling Process:**
To fill a Schedule 2 order, the Controlled Substance Vault Clerk must verify the Schedule 2 Order Form information and the work order information are the same and correct. The Clerk must then go to the location indicated on the work order for the item and select the quantity ordered. Once the item quantity has been selected, the National Drug Code (NDC) number listed on the product container must be verified against the work order NDC number.

The quantity shipped and the date shipped must be entered in the appropriate spaces to the right of the NDC number column. Generic substitution requires the NDC number to be entered for the actual product shipped. The DC's DEA Registration number is also entered in appropriate block.

**NOTE: ENSURE THE "DATE SHIPPED" ANNOTATED ON DEA FORM 222 ACCURATELY REFLECTS THE DATE THE PRODUCT ACTUALLY LEAVES THE DC AND THAT THE CORRECT SHIP DATE IS REFLECTED ON THE INVOICE.**

National Drug Code (NDC) numbers on the controlled substance containers must be checked against the NDC number listed on the work order both at the time the item is

removed from the shelf and during the double checking process on Schedule 2 & 2N controlled substances.

All Schedule 2 & 2N controlled substance orders filled must be double checked after filling and prior to packing by an associate other than the associate who filled the order.

The Schedule 2 orders must be retained in the vault area until a "compliance critical" associate picks them up prior to departure of the delivery vehicle.

The "compliance critical" associate, when picking up the Schedule 2 orders from the vault, must verify the presence of and accuracy of Schedule 2 shipments against the Schedule 2 Product Log or Checklist Manifest. The Schedule 2 Product Log or Checklist Manifest must be signed by the driver as proof of his possession of the orders until delivered.

***21 CFR 1305.13 Preservation of order forms***

*(a) The purchaser shall retain Copy 3 of each order form which has been filled. He/she shall also retain in files all copies of each unaccepted or defective order form and each statement attached thereto.*

*(b) The supplier shall retain Copy 1 of each order form which he/she has filled.*

*(c) Order forms must be maintained separately from all other records of the registrant…*

After all Schedule 2 controlled substance orders are filled for the day, the Schedule 2 order forms and work orders must be filed separately from all other records.

Schedule 2 order forms filled by the DC must be reviewed by the close of each month by the DCM, Compliance Coordinator, or other designated manager or supervisor to ensure proper review for defective order forms is being accomplished by Schedule 2 Order Clerks.

## D. SCHEDULE 2 BACKORDERS AND OMITS

If Schedule 2 product is backordered, draw a diagonal line (*/*) in the Packages Shipped and Date Shipped spaces on the DEA Form 222, and indicate the quantity filled on one side of the box. Enter the balance of the back-ordered product once the order is filled.

Cancel the unfilled quantity on the DEA Form 222 if the balance cannot be filled within 60 days of the date on the DEA Form 222. A customer may reorder the product on another DEA Form 222 when the product arrives.

## E. PERMISSIBLE SUBSTITUTIONS FOR SCHEDULE 2 ORDERS

If the package size or strength is not supplied as listed on the order form, we may ship one or more of a lesser size as long as we do not exceed the total amount ordered. For example, we may ship 5 x 100 on an order instead of 1 x 500 if 500's are not produced or not in stock. We are also permitted to ship a reduced strength if the strength ordered is not produced or is not on hand.

We may **NOT** fill an order with a higher strength item. For example, an order for 50 mg. may be filled with 30 mg., only if 50 mg. is not made. A 60 mg. item could not be filled since it is a higher strength than ordered.
In such an instance, the customer **must** be contacted to determine if he desires such a substitution to be made.

## F. SCHEDULE 2 CONTROLLED SUBSTANCES SHIPPING CONTAINERS

**No markings, labels, paperwork, or any other method of identifying the contents of Schedule 2 packages or parcels are allowed by federal regulations.**

## G. LIFE-THREATENING SITUATION

On occasion, a request may be made by a customer to provide a Schedule 2 item in an actual emergency situation when the Schedule 2 order form cannot be provided to the company before shipment. **This transaction will require prior approval from the DEA office before shipment is possible.**

Any contact with the DEA office must be recorded on a **Government Contact Form, CSRA Form #2 with a copy attached to the order form** when the order form is received. The original order form and DEA contact information must be filed in the daily order form file for the date the order was actually shipped.

## H. SCHEDULE 3, 3N, 4, AND 5 CONTROLLED SUBSTANCES

Orders for these items are filled using the same work order format as our regular, non-controlled product. DEA Form 222 is not required for Schedule 3-5 items.

After the Schedule 3-5 controlled substances have been checked and packed for shipment, they must remain in the cage until a “compliance critical” associate picks them up prior to departure of the delivery truck. If Schedule 3-5 controlled substances are taken from the cage prior to departure of the delivery vehicle they must be maintained under constant supervision at all times while outside the cage. The “compliance critical” associate, when picking up the Schedule 3-5 orders from the cage, must verify the presence of and accuracy of the shipments against the Checklist or Delivery Manifest. The Checklist and/or Delivery Manifest must be signed by the driver, as proof of his possession of the orders until delivered.

## I. SCHEDULE 3, 3N, 4, 5 CONTROLLED SUBSTANCE SHIPPING CONTAINERS

**No markings, labels, paperwork, or any other method of identifying the contents of Schedule 3-5 packages or parcels are allowed by federal regulations.**

## J. "WILL CALL" PROCEDURES

Discourage "Will Calls" of Schedule 3-5 product, and Schedule 2 product can only be "will called" on an emergency basis.

Before we can release any controlled substances to any individual in a "Will Call" situation, we are required to confirm by a return telephone call to the customer, the name of the person who will be picking up the order. This information may be keyed as part of the order and appears in the "message field" of the work order and invoice. When the person arrives, the Warehouse Supervisor or other authorized associate asks for identification (driver's license). The person picking up the order signs the **Will Call Log, CSRA Form #14** and the Warehouse Supervisor or other authorized associate dates and initials it. The associate records the driver's license number and the person's name on the work order and the Will Call Log.

**Note: A completed DEA Form 222 must accompany any Schedule 2 order from the customer.**

**Prescription Drug Will Call Policy**

i. Purpose:
The purpose of this policy is to control the movement of product from the DC and ensure that product shipped via Will Call transactions are released to authorized personnel only.

ii. Policy:
(1) Will Call transactions should only take place in emergency situations.

iii. Procedures:
(1) Will Call transactions will only be released by a Manager/Supervisor or other designated individual.
(2) When a Will Call transaction is approved by the DCM, or his/her designated representative, the following actions will take place:
(a) A copy of the invoice or picking document will be made and attached to the order.
(b) The product will be staged in a secure area away from all building doors.
(c) Should the Will Call involve controlled substances, the order will remain in the DEA approved secured area until released.

(d) The person picking up the Will Call order will be positively identified by viewing a photo ID, driver's license, etc.

(e) If the person picking up the order is not known to the manager/supervisor, then a call is to be made to the customer to verify the identity of the person.

(f) The individual picking up the order is required to sign for the order on the invoice or picking document that will then be placed in file for retention.

## K. FILING OF COMPLIANCE RECORDS, DOCUMENTS AND INFORMATION

Due to the high level of documentation and accuracy required by DEA regulations, it is extremely important that all records, documentation and information regarding controlled substance transactions be maintained in an accurate and readily retrievable manner.

When transaction records, documentation and information are prepared and completed, **immediate filing** in the appropriate file locations must take place. These records, documents, and information are not to be allowed to accumulate on desks, in drawers, or other locations under any circumstances but are to be placed in proper file locations. File cabinets are provided and maintained in the vault and cage areas for the filing of this information.

## L. PURGING OF COMPLIANCE RECORDS

A monthly review of records, documents and other information files is to be conducted for the purpose of "purging" and deleting any records containing dates beyond three years.

A list of records required to be maintained beyond the above three-year time frame is posted on the vault and cage bulletin boards. These generally relate to certain inventories; Power of Attorneys; DC registration applications and renewals; and other various items. Check with your State regulatory authorities, as their requirements may be more stringent.

## SECTION 6

## SHIPPING PROCEDURES

### A. SHIPPING DOCK SECURITY

Shipping dock areas are "Restricted Areas" and "Off limits" to all but department associates and only company associates requiring access to the area in performance of their normal job duties. Smoke, coffee, lunch or any other type breaks are prohibited in the shipping area. The company provides a break room for this purpose.

Shipping and receiving areas must be physically separated if possible. If necessary, install a permanent barrier such as chain link fencing between the two areas.

Shipping dock doors are to remain closed and incapable of being opened from the outside, except when trucks are entering or leaving the dock area, or are in the process of being loaded or unloaded and such activity prevents the doors from being closed.

Doors required to be opened for ventilation or other reasons must be equipped with expandable metal gates (scissor gates) or grating properly installed to prevent unauthorized access to the dock area.

***21 CFR 205.50(b)(1)(iii):*** *Entry into areas where prescription drugs are held shall be limited to authorized personnel.*

Sufficient barriers or procedures must be present at the shipping dock which prevents commercial drivers or other persons from entering the warehouse area or areas of the building other than the shipping dock.

All non-associates, including contract and common-carrier drivers, must be accompanied by an associate when present in the warehouse or office areas.

Associates' personal vehicles must be parked in designated associate parking areas, more than 50 feet away from the shipping and receiving docks.

### B. CONTROL OF ORDERS

All controlled substances must remain in the DEA approved security enclosure (cage/vault) or maintained under "constant supervision" until just prior to the final loading process and departure of the delivery vehicle.

Controlled substances must not be left unattended or unsupervised in the shipping dock area.

A documented chain of custody, either electronic or manual, must be maintained in order to verify that all controlled substance orders leaving the cage or vault area are received at the shipping dock by another "compliance critical" associate.

Controlled substance orders must be listed and identified separately on the delivery manifest to facilitate identification of the order and obtaining the customer signature at the time of delivery.

Controlled substances must be signed for at the time of delivery to the customer.

Controlled substances must be delivered **only** to the address printed on the address label on the shipping container. If the address on the shipping label is not correct, or is in error in any way, **the controlled substances MUST be returned to the DC** until the variance in the address has been properly researched and corrected.

Upon the driver's return to the DC or terminal, the Shipping Supervisor or other "compliance critical" associate must check all delivery paperwork to verify proof of delivery of controlled substances. All manifests and controlled substances proof of delivery documents must be maintained on file in the DC for seven (7) years.

**AmerisourceBergen Drivers**

When one of our drivers picks up a package from the cage or vault, he or she must verify that the total number of packages is listed on the Schedule 2 Product Log or Checklist Manifest. Each package must also be verified against the driver's manifest. Once the driver signs the log, he or she is responsible for the product.

## C. COMMON AND CONTRACT CARRIERS

***21 CFR 1301.74(e)*** *When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses…*

The **"AmerisourceBergen Corporation Guidelines, Policy and Procedures Manual for Common Carriers", CSRA Form #25** must be used to evaluate common or contract carriers. In addition, the **"Selection and Evaluation Checklist for Carriers"** must be completed and placed in file at the DC. A copy of the initial checklist must be forwarded to the Corporate Security and Regulatory Affairs Department for review. An Evaluation Checklist must be completed annually thereafter for all carrier's facilities and placed in file at the DC.

## D. FREIGHT FORWARDING FACILITIES

Each Distribution Center must have authorization in file from DEA to operate ALL freight forwarding facilities under their control. In addition, the DC must maintain documentation to reflect the time and date controlled substances enter and exit the freight forwarding facility. Controlled Substances must not be stored in a freight forwarding facility for more than 24 hours and must be maintained under constant supervision while in the freight forwarding facility. Transfers of controlled substances between the DC and freight forwarding facilities must be transported by AmerisourceBergen associates or a dedicated carrier.

## E. NARCOTIC TREATMENT PROGRAMS

***21 CFR 1301.74(h):*** *The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.*

In order to meet the above requirements, the following policy must be followed. Before selling methadone to a Narcotic Treatment Program (NTP) facility, a **Narcotic Treatment Program Authorized Signature Form, CSRA Form #27** containing the name(s), specific job title(s) and signature(s) of persons authorized by the licensed practitioner (generally the individual who signed the last DEA registration or application for registration) must be obtained and maintained in file at the DC for the period of time the customer is serviced plus three years.

DEA has approved the use of a signed delivery manifest in meeting this regulation. Whichever paperwork is used by the DC, the names authorized to receive the methadone shipments may be printed by the computer on the invoice or delivery manifest so that the delivery driver will know to whom the shipment can be legally delivered. A procedure must be developed by the DC to insure these signed delivery documents are obtained, returned to the DC, verified against the authorized signature record and filed at the DC as required by 21 CFR regulations.

## SECTION 7

## RETURNS PROCEDURES

### A. CONTROLLED SUBSTANCE RETURNS

The proper handling and recording of controlled substance returns from customers is a very important portion of our controlled substances recordkeeping program. The same accountability and security required in the receipt or shipment of controlled substances into or from our building must apply when these items are returned to us from customers.

Controlled Substance return policy must require the customer to contact the DC and request approval for the return of controlled substances. This may be accomplished by telephone or electronically to produce a Return Authorization (RA). At the time of contact, the customer must be instructed how to return the controlled item(s); either by driver pickup (with proper driver pickup documentation), by UPS, or by other method. The customer must also be advised that the return authorization involves **only controlled substances;** that the controlled substances are to be segregated from all other product; and packaged separately for return.

***21 CFR 1305.03 Distributions requiring order forms***
*An order form (DEA Form 222) is required for each distribution of a Schedule I or II controlled substance except for persons exempted from registration under part 1301 of this chapter.*

**Note: DEA Form 222 is required for the return of a Schedule 2 or 2N item.**

**Only Unopened Containers of Controlled Substances Stocked by the DC Will Be Accepted.**

**Upon return of controlled substances to the DC,** a "compliance critical" associate signs for the package(s) and takes it **immediately to the cage or vault area for proper processing of the credit.** In the event no associates are present in the cage or vault area, the returned controlled substances must be given directly to the Shift Supervisor and maintained under constant supervision.

***21 CFR 1304.21(d)*** *In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).*

**NOTE: ALL CONTROLLED SUBSTANCES MUST BE RECEIPTED AND**

**STORED IN THE VAULT OR CAGE ON THE DATE ACTUALLY RECEIVED.**

**Under no circumstances are controlled substance returns permitted to remain overnight in a delivery vehicle or over 24 hours in a freight forwarding facility (cross dock/depot). Controlled Substance returns must be maintained under constant supervision while in the freight forwarding facility.**

Any item(s), which cannot be accepted for return, may be returned to the customer. A **"Product Return to Customer Form", CSRA Form #20** must be used to explain the reason for the return and to obtain a customer signature for proof of delivery. This form must be returned to the DC. This form is filed with all controlled substances proofs of delivery.

**Any controlled substance that arrives at the DC without paperwork or other indication of the source of the item must be added to inventory.**

**Distrack DCs** must establish an account in the customer file entitled **"Unsolicited Return-Controlled Substance" and assign the DC's DEA number to the account.** Should any controlled substance arrive at the DC without paperwork or other indication of where the items came from, the item number(s) for the controlled substance(s) must be entered as any other credit return.

**STAR DCs** must utilize an "OA" adjustment to add the unsolicited return into inventory and, if the item is reportable, create a record in ARCOS maintenance to report the unsolicited return to ARCOS.

Controlled substances which are damaged, broken, outdated, or otherwise nonsaleable, whether being returned from customers, or occurring in the building, will only be stored in the cage (Schedule 3-5 items) or vault (Schedule 2 and 2N items).

**B. PRESCRIPTION DRUG RETURNS**

Return Authorizations (RA) must be signed by the customer certifying that prescription drugs have been stored under the proper conditions while in the customer's possession.

In-bound customer returns must be sorted on a daily basis to ensure items requiring refrigeration are placed in appropriate storage areas in a timely manner.

The DC's Rx non-saleable (morgue) storage area must be adequately segregated from storage areas for saleable products of the same type.

***21 CFR 205.50(e)*** *Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to their supplier.*

The purpose of this policy is to define the procedures to be followed to control outdated, damaged, deteriorated, misbranded, or adulterated products that arrive at, are returned to, or are found in the DC.

Pharmaceutical products generally have a specific shelf life that is determined by the expiration date printed on the package or label. If this expiration date is reached, specific steps must be followed to remove the product from the distribution channels and ensure that it does not re-enter the channels.

**Quarantine Area for Damaged, Outdated, Unsaleable Products:**

The Returned Goods area within the DC has been designated as the repository for damaged, outdated, misbranded, adulterated, or opened pharmaceutical products. This area is capable of keeping these products segregated from the general areas of the warehouse pending disposition action. The Returned Goods Department will be located in a manner that will limit traffic into or through the area and preclude the inadvertent movement of quarantined product back into the general warehouse areas.

Where possible, the area will be located and constructed so that it can be secured to prevent entry by unauthorized personnel. When this is not feasible, the area should be clearly marked as the "Returned Goods Area - Authorized Personnel Only."

A separate quarantine area for Schedule II, III, IV and V controlled substances will be required and established in the vault and cage areas as appropriate.

Controlled substance non-saleable (morgue) storage areas must be adequately segregated from storage areas for saleable products of the same type.

An inventory must be maintained in a current and up-to-date manner for any controlled substances being placed into nonsaleable status.

**Damaged Product:**

**Incoming Product:**
Obvious damage should be refused at the dock and not be allowed to enter the building. Exceptions to this policy should be kept to a minimum and cleared by the receiving or warehouse manager.

Concealed damage that is discovered in the receipting or storage process, after the product has been signed for, should be clearly marked as damaged, deducted from inventory and immediately removed to the Returned goods area for quarantine.

**Damage occurring within the building:**
Product sustaining damage within the DC, (i.e., dropped, hit by material handling equipment, etc.) must be immediately taken to the Returned Goods Area for segregation and deducted from inventory.

**Damage during delivery:**
Product damaged during delivery or returned by customers must be delivered directly to the Returned Goods Area.

The product will be inspected for apparent or concealed damage. This inspection will include, but is not limited to, inspection of the sealed outer and sealed secondary containers to see if they have been opened and/or product used. If any damage or deterioration is found, the product will be quarantined and held for inspection and disposition by manufacturer representatives, or disposed of in accordance with manufacturer instructions.

**Under no circumstances will damaged product knowingly be placed into stock.**

**Outdated Product:**

Product from within the warehouse that is discovered to be outdated, or "short-dated" as part of the Stock Rotation Program inspections, will be deducted from saleable inventory and immediately taken to the Returned Goods area. Product discovered at the Receiving Department to be outdated/short-dated, prior to signing for the shipment, will be refused. If found after signing for the shipment, the procedures above will apply.

All product returned from customers will be taken directly to the Returned Goods Department and as part of the normal inspection process, expiration dates will be checked.

1. Any product found to be outdated/short-dated, will be segregated into the manufacturer "bin" or holding area and held for disposition action by the manufacturer representative.

**Recordkeeping Requirements for the Returned Goods Department:**

Records of all product dispositions must be maintained for a period of three (3) years from the date of disposition.

All product returned from customers must be accompanied by documentation indicating the description of the product(s) returned, the reason the product is being returned, the name and address of the customer returning the product, and the date of the return.

The above documentation must be annotated by the Returned Goods Department to indicate the disposition of the product, i.e., whether the product was placed back into stock or was held awaiting disposal disposition.
A copy of all documentation must be maintained in the Returned Goods Department, customer credit file, or on computer files which accurately records all product return transactions (a) coming back into the building, (b) maintained in the Returned Goods Department, and (c) being placed back into inventory.

**Disposition of Product:**

Disposition of product will be in accordance with manufacturer's policies and all applicable local, state and federal regulations and law pertaining to waste disposal. It is preferred that all returned product be returned to the manufacturer to limit risk and liability exposure against the DC.

## C. CONTROLLED SUBSTANCES RETURNED TO SUPPLIER/VENDOR

Nonsaleable Schedule 2 product can be returned **only** upon receipt of a completed DEA Form 222. In addition to standard return-to-supplier procedures, take the following steps.

**To Return Nonsaleable Schedule 2s to Supplier:**

1. Upon receipt of the DEA Form 222 from the supplier, complete AmerisourceBergen's sections of the DEA Form 222.
2. Pack the items, keeping Schedule 2s separate.
3. The carrier signs the Schedule 2 Product Log when he or she picks up the box.
4. Once the Debit Memo or Returned Goods (RG) is generated, write **DM** or **RG** and the last four digits of the DM or RG number in the upper right-hand corner of the DEA Form 222.
5. File the top copy of the DEA Form 222. Send the second copy to the DEA no later than the 15th of the following month.

**To Return Nonsaleable Schedule 3-5s to Supplier:**

Returning nonsaleable Schedule 3-5 product to the supplier involves Debit Memos or RGs just like in returns for other prescription drugs, except with the following differences:

- Items are listed on separate Debit Memos or RGs.
- Items are shipped in a separate box.

{PRIVATE}All controlled substances must be shipped to the supplier or third-party processor the same day of Debit Memo/RG generation. The current date must be on the Debit Memo/RG when it is created. Attach all shipping label receipts to the debit memo to indicate tracking number and date shipped. If controlled substances or listed chemicals are shipped to an authorized destruction firm, the destruction firm's correct address must be printed on the Debit Memo or RG.

**D. CONTROLLED SUBSTANCE, LISTED CHEMICAL AND PRESCRIPTION DRUG DESTRUCTION**

**Controlled Substances:**

Any outdated, damaged, or nonsaleable Schedule 2-5 controlled substances that cannot be returned to the supplier must be sent to a third-party processor for destruction. Contact your DEA office for specific instructions on arranging for destruction of Schedule 2-5 product in your local jurisdiction. Alternately, write a letter to the local DEA office requesting authorization to have the product destroyed through one of their burn-site facilities.

**Note: AmerisourceBergen does not itself destroy product, whether controlled substance or otherwise.**

When shipping the product to be destroyed by the DEA, follow the proper procedures using Registrant's Inventory of Drug Surrenders (DEA Form 41):

- Make three copies of DEA Form 41. Send the original and two copies to the local DEA Office and keep one for your files.
- Forward the items to the DEA.
- When you receive proof of destruction, forward a copy of DEA Form 41 to Data Processing to request credit from the supplier.
- Indicate on the Debit Memo that the product was destroyed.
- Indicate the last four digits of the Debit Memo number on DEA Form 41, and file the form.
- Send a copy of the DEA Form 41 and the Debit Memo to the supplier for credit on the product.
- Proof of delivery is required for all packages shipped for destruction.

**Listed Chemicals:**

A record must be maintained at the DC for all listed chemicals returned to supplier or destroyed.

**Prescription Drugs:**

Any outdated, damaged, or nonsaleable prescription drug product that cannot be returned directly to the supplier must be sent to a third-party processor for proper disposition. A complete record must be maintained at the DC for all prescription drug product returned to the supplier or destroyed. This record must contain the quantity, name of the drug, strength, size, date shipped and to whom it was shipped.

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**Note: AmerisourceBergen does not itself destroy prescription drug product.**

## E. WASTE DISPOSAL

There are many reasons why a product may need to be transferred to a third-party processor from one of our facilities (breakage, improper storage, being outdated, etc.). All nonsaleable, nonreturnable product at any AmerisourceBergen facilities must be professionally handled and cannot be discarded into a dumpster or garbage can. Failing to monitor what is discarded into disposal receptacles places AmerisourceBergen in jeopardy of violating state or federal regulations and subject to various fines and penalties. All nonsaleable, nonreturnable products should be handled through a licensed, reputable third-party processor or as specific state regulations require. It is crucial that each AmerisourceBergen facility stay up to date with their state-specific guidelines regulating waste disposal.

A simple rule of thumb is:

- Any item used in or on the body, whether liquid, powder, or solid, should always be disposed of properly.
- This includes packaging materials for such products. Regardless of how harmless a product may seem, it can become dangerous. AmerisourceBergen associates should not make the determination about re-use or disposal of any product.
- 3E Company can assist in identifying questionable products and can provide methods of disposal that comply with state and federal regulations.
- If you have any questions or concerns regarding hazardous waste handling or waste disposal, contact the Corporate Security and Regulatory Affairs department.

## SECTION 8

## RECORD KEEPING PROCEDURES

### A. STORAGE OF CONTROLLED SUBSTANCE RECORDS

***21 CFR 1304.04(f)***

> ***(1)*** *Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the records of the registrant; and*
> ***(2)*** *Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.*

All primary records relating to controlled substances transactions, or the AmerisourceBergen Regulatory Compliance Program, must be maintained on file in the location and readily retrievable for the period of three years from the date of the record.

Ensure that the following Schedule 2 primary records are kept separate from all other records:

- DEA Form 222s
- Inventories
- Invoices
- Receiving Documents
- Debit Memos/RGs
- Credit Memos/Return Authorizations

Ensure Schedule 3–5 primary records of the above kinds are always readily retrievable. This can be accomplished by either storing the records separately or storing photocopies of the records separately.

### B. CUSTOMER DEA REGISTRATION VERIFICATION

***21 CFR 1301.74(a)*** *Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a "good faith" inquiry either with Administration, or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.*

DEA has stated that the presence of a customer's DEA registration certificate in file will serve to meet the "good faith" inquiry requirement. Therefore, a legible copy of a new customer's DEA certificate **must be obtained and placed in file prior to the filling of**

**any controlled substance order for that customer.** The DEA certificate must be checked for the presence of a "full schedule authorization" to purchase all schedules (2, 2N, 3, 3N, 4 and 5) of controlled substances. The DC must restrict purchases of controlled substances that are not authorized on the DEA certificate. The certificate must contain the date of receipt by the company and the initials of the associate entering the information into the system.

Customer computer file information must contain all information **exactly as it is listed on the customer's DEA registration certificate.**

A review of the "Sales Manager Exception Report" (NTIS) must be conducted monthly to ensure accuracy of AmerisourceBergen data entry compared to what the DEA has loaded for that customer. The NTIS report used for this verification process must be signed and dated by the associate making the verification and filed for three years.

For DCs without access to NTIS data, a review of the customer registration certificates on file against information contained in the computer customer file **must be conducted at least semi-annually** for accuracy. Printouts used for this verification process must be signed and dated by the associate making the verification and filed for three years.

## C. CUSTOMER DEA REGISTRATION/STATE LICENSE RENEWAL PROCEDURES

A corporate approved program must be present to verify the customer's DEA registration at the time of expiration of the registration. The program must include obtaining a copy of the customer's renewed DEA registration certificate and placing the renewal copy in the customer file or in a DEA registration certificate file. If the copy of the customer's renewed DEA *registration* certificate has not been received **by the date of expiration printed on the current certificate, the customer's ability to purchase controlled substances must be removed as of the date of expiration.**

The Code of Federal Regulations (CFR) states that a registrant may apply to the DEA for renewal not more than 60 days before the expiration date of the current registration. There is no formal grace period extended.

The DC must monitor the DEA Expiration Report, showing all customers whose registration expires within 60 days. The DC notifies the customer and informs them that it is time to renew. When the customer receives their renewed certificate, the DC is responsible for obtaining a copy of the certificate and verifying its completeness to ensure that the customer is licensed in each Schedule. If a certain Schedule authorization is missing from a customer's DEA Registration, AmerisourceBergen cannot ship the customer products of that Schedule. The DC must notify the customer of the missing Schedule so that they can obtain a "corrected certificate" from DEA. It is the DC's responsibility to comply with the DEA requirement that all customers purchasing controlled substances have a valid and current DEA registration.

**To Verify Customer DEA Registration Renewal**

1. Use the DEA Expiration Report to monitor expiration dates on our customer's DEA registration.
2. Check all customers whose DEA registration will expire within 60 days to verify that they have applied for renewal or have received their new registration.
3. When customers have not received their renewal application 45 days prior to the expiration date, it is their responsibility to contact the DEA, in writing.
4. Verify that those customers whose registration will expire within 30 days have received a new Registration Certificate.
5. The day the customer's DEA registration expires, call the local DEA office to verify that it is okay to ship product (controlled substances) to the customer. Be sure to fill out the Government Contact Form. At no time should a customers DEA registration expiration date be extended for more than 30 days.
6. Repeat the above procedure every 30 days until the customer receives a new DEA Registration certificate.
7. Keep all customer Registration Certificates up-to-date in case of a DEA or AmerisourceBergen audit.
8. Anytime an account changes its name, ownership, or address, it is recommended that you check with the DEA and your State Board of Pharmacy regarding validity of the account's license or registration.

**NOTE: Drivers, Sales and marketing associates or other company associates who become aware of a customer who anticipates relocating their business, selling their business, or turning over day-to-day management of their business to another party should immediately provide this information to the DC.**

**To Verify Customer State License**

If a customer is required to be licensed by a state regulatory authority (Board of Pharmacy, Department of Health, etc.) to purchase or handle prescription (Rx) drugs or listed chemicals, then DCs should also verify customers' state license certificates by obtaining a current copy of the customer's state license and placing it in file. The customer's state license number and expiration must be loaded in the system and kept up to date.

A physical copy of the each customer's state license is required, however, customer state license renewals may be verified on-line at the applicable state authority web site in lieu of obtaining a hard copy of the customer license renewal. A copy of the current state license verification must be printed and retained in each customer file.

## D. PDMA CERTIFICATION AND REPRESENTATION AGREEMENT

The FDA has established guidelines for the return of product from hospitals and health care entities. These guidelines are set forth in the **Certification & Representation Agreement, CSRA Form #5** that AmerisourceBergen requires each hospital and health care entity to sign. A signed agreement must be obtained from every account that receives contract pricing from the manufacturer and that falls under the definition of a Health Care Entity as stated in the Certification & Representation Agreement. When in doubt as to whether an account requires a customer signed CARA, it is AmerisourceBergen policy that one should be obtained. CARAs should be maintained in the customer account files and should be updated every three years.

## E. LISTED CHEMICAL LICENSING REQUIREMENTS

As part of the implementation of the Methamphetamine Control Act (MCA), all AmerisourceBergen customers are required to meet one of the three following criteria in order to purchase listed chemical products:

1. Possess a current DEA Controlled Substance Registration Certificate.
2. Possess a current DEA Listed Chemical Registration Certificate.
3. Be considered a **Retail Distributor**—defined by the MCA as "a grocery store, general product store, drug store or other entity or person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in the number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales."

If any AmerisourceBergen customers fall under the retail-distributor classification and are not required to have a DEA registration in order to purchase listed chemical products, the following procedures must be followed to enable the customer to order listed chemicals:

a. Have the customer complete a **Retail Distributor Representation Agreement, CSRA Form #6** and enclose the completed form in the customer file
b. Enter **CHEMONLY** in the DEA number field in the STAR system or change the “METHAC Sales Prohibited” flag to “N” in the Distrack System

## F. STATE LICENSING EXEMPTIONS

Depending upon the domiciliary state, certain classes of trade (surgery centers, closed-door pharmacies, etc.) may be exempt from state-level licensing. If a customer claims to be exempt from state-level licensing, the following conditions must be met:

1. The DC should contact their state's regulatory authority. If it is confirmed and the customer is exempt, documentation of such should be maintained in the customer's file using a Contact Form.
2. Type the word **EXEMPT** into the **State License** field of the Customer Maintenance File. For the **Expiration Date** field, the DEA registration expiration date should be repeated. Under no circumstances should a generic or fictitious number (**999...**) be entered into the state license field.
3. If the customer does not purchase controlled substances (therefore, no DEA registration) and is exempt from state-level licensing, the DC should obtain a copy of the license of the physician who will be responsible for the handling and security of Rx drugs sent to that specific location. A "statement of responsibility" should be drafted by the DC, signed by that physician, and maintained in the customer's file.

## G. CUSTOMER FILE UPDATES

Ensure registration or license documentation is continually updated in all customer files. Customer files are subject to DEA, state, and AmerisourceBergen inspection.

## H. CENTRAL RECORDKEEPING AUTHORIZATION

The computer records for the DCs are located either in Chesterbrook, PA or Orange, CA. Any computer file information must be obtained from AmerisourceBergen Information Resources (IR) in Chesterbrook, PA or Orange, CA. DEA has been notified in writing of this central recording keeping process, and ARCOS reports are created under a central reporting number.

## I. POWER OF ATTORNEY AUTHORIZATION TO ORDER SCHEDULE 2 ITEMS

***21 CFR 1305.07 Power of attorney***

*Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his/her behalf by executing a power of attorney for each such individual. The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and by the individual being authorized to obtain and execute order forms. The power of attorney shall be filed with the executed order forms of the purchaser, and shall be retained for the same period as any order form bearing the signature of the attorney. The power of attorney shall be made available for inspection together with other order form records. Any power of attorney may be revoked at any time by executing a notice of revocation, signed by the person who signed (or was authorized to sign) the power of attorney or by a successor, whoever signed the most recent application for registration or reregistration, and filing it with the power of attorney being revoked.*

When executing orders for Schedule 2 or 2N controlled substances, Schedule 2 order forms (DEA Form 222) can only be signed by specifically authorized persons. The individual who signed the last registration application for the DC is authorized to sign Schedule 2 order forms and is authorized to grant Power of Attorney allowing other persons to sign Schedule 2 order forms. Only this individual can grant or revoke Power of Attorney authorization.

A Power of Attorney Authorization contains the name and signature of the person who is being given authorization to sign order forms. The authorized individual could allow one or more persons to sign Schedule 2 order forms; however, **each** person must have a current Power of Attorney authorization form in file during the period of the authorization.

Should the authorization be revoked or rescinded, a revocation form must be prepared and placed in file indicating the original authorization has been revoked. These documents have been combined into one **Power of Attorney/Revocation Form, CSRA Form #3** for use by AmerisourceBergen DCs.

The above Power of Attorney process would also apply to our customers including pharmacies, hospitals, or practitioners.

The format for these authorization documents is explained in 21 CFR 1305.07.

## J. REQUESTS FOR INFORMATION

On occasion the Drug Enforcement Administration, or state regulatory authorities may request drug transaction reports as part of an investigation they may be conducting. These agencies have every legal right to request such information and you, as a registered distributor with these agencies, are required to provide such information.

Every attempt should be made to provide this information within the shortest period of time possible, but in no case should providing such information exceed forty-eight hours.

Any requests for information from government agencies must be made **in writing** by the agency either by letter or administrative subpoena for the protection of our company.

**All** requests for information from government agencies **must be forwarded to the Corporate Security and Regulatory Affairs Department** before this information is provided to such agencies.

## SECTION 9

## INVENTORIES

### A. GENERAL

***21 CFR 1304.11(a)*** *Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location…*
*Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in possession of employees of the registrant…*
*The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.*

There are several reasons for conducting frequent inventories of controlled substances and listed chemicals -- some are voluntary, some are mandated by federal regulations.

### B. CORPORATE REQUIRED CONTROLLED SUBSTANCE INVENTORIES

**Daily Activity Counts:**

AmerisourceBergen DCs must conduct **daily** activity counts of **all** controlled substances having any type of activity (adjustment, receipt, return, sale, etc.) on the previous day. The daily activity counts provide early detection and resolution of any discrepancies that may occur between the computer on-hand figures and the actual on-hand quantities for each controlled substance. The associate(s) taking the inventory must sign and date the top of the report.

**Monthly Inventories:**

A **monthly** inventory of **all** controlled substances, saleable and nonsaleable, must also be conducted. Although monthly inventories are not required by regulation, AmerisourceBergen voluntarily conducts them to maintain accurate records and accountability, which **is** required by federal regulations and corporate policy. Controlled substances inventories should be conducted as of the "close of business" on the last business day of each month if possible**.**

**NOTE: All monthly controlled substance inventories must be annotated on the first page of the report that the inventory was taken either as of the "opening of business" or as of the "close of business" on the inventory date. The associate(s) taking the inventory must sign and date the top of the report.**

Vault and cage order fillers should not perform inventories in their respective order-filling areas. The associate who conducts the physical inventory in the vault should not be the same associate who is responsible for order filling in the vault; likewise, the associate who conducts the physical inventory in the cage should not be the same associate who is responsible for order filling in the cage. If staffing requirements necessitate vault and cage order fillers assisting in these counts, a supervisor should simultaneously count with the order filler or spot check the inventory counts.

## C. CORPORATE REQUIRED LISTED CHEMICAL INVENTORIES

All listed chemical products must be inventoried **quarterly**. A physical inventory of bulk containers (bottles of 60 or more) of listed chemicals must be conducted on a **monthly** basis.

Note at the top of the report whether the inventory was taken as of the "opening of business" or "close of business". The associate taking the inventory must sign and date the top of the report.

## D. DEA REQUIRED INVENTORIES OF CONTROLLED SUBSTANCES

### Initial Inventory

When a DC is initially assigned a DEA registration number, it is required to complete a physical inventory of all controlled substances on hand. This inventory is the DC's opening physical inventory.

### Biennial Inventory

***21 CFR 1304.11[c]*** *After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.*

Federal regulations require that every two years following the opening inventory date, a new physical inventory of all controlled substances must be conducted. This inventory must be specifically annotated as the **Biennial Inventory**, and the top of the report must indicate whether the inventory was taken as of the "opening of business" or "close of business." The associate taking the inventory must sign and date the top of the report.

With the recent changes regarding the biennial inventory it is important to understand that the established biennial inventory date determines when your next biennial inventory must be taken. Under the new requirements, the biennial inventory must be taken **within two years of the last biennial inventory.** This means that you cannot go beyond the two-year date or you will be in violation of 21 CFR regulations.

**NOTE: AmerisourceBergen has chosen December 31st of every even-numbered year as the Biennial Inventory date for all DCs.**

**ARCOS Year-End Inventory**

The DEA requires that each DC perform a year-end inventory of all ARCOS reportable controlled substances. The annual ARCOS inventory is performed by all DCs at the end of the last business day of the calendar year. All counts, both saleable and nonsaleable, must be submitted to the ARCOS Unit of the DEA. These counts must include all reportable controlled substances on hand in the building as of the "close of business" December 31. Submission of the year-end inventory to the DEA is done by running a special job after running the last receiving End of Day for the year, and after processing all orders that are to be shipped prior to January 1.

## E. GENERAL INVENTORY REQUIREMENTS

It is the intent of AmerisourceBergen to maintain a complete and accurate inventory of all products at all times. This is particularly true with prescription drugs and any transaction or inventory errors involving these items are to be immediately corrected within the computer system to maintain accuracy.

While conducting inventory of prescription drugs, the individual conducting the inventory will visually inspect the items for the proper identity and placement of the items, to determine the item is within the expiration date, that the items are properly stocked with the shortest expiration date to the front of the shelf, and that the items are not damaged or otherwise unsaleable.

Inventories and other documents relating to controlled substance inventories must be filed in a location known to the DCM, Compliance Coordinator, and others in the company in *the* event the DCM is not present at the time of compliance audit or DEA inspection is initiated.

All AmerisourceBergen required monthly controlled substance inventories and all DEA required controlled substance inventories must be supervised, verified and signed by a DC management official other than the Compliance Coordinator.

Any variances between computer on hand figures and counts taken during inventories of controlled substances **must be researched immediately** to determine the cause for such variance and for initiation of proper documentation and correction. Correction of such variances must be supported by appropriate documents which properly update computer history.

In each case, the variances must be researched for proper explanation as to the cause for the variances. Thefts or significant losses discovered during controlled substance inventories must be reported to the CSRA department and DEA in accordance with **AmerisourceBergen Theft and Loss Policy** in Section 12 of this manual**. A copy of all documents provided to DEA must be forwarded to the Corporate Security and Regulatory Affairs Department.**

## F. CONTROLLED SUBSTANCE/LISTED CHEMICAL INVENTORY ADJUSTMENTS

Before any controlled substance or listed chemical adjustments are made, an **Inventory Adjustment Form, CSRA Form #24** must be signed by the preparer and approved and signed by either the Inventory Manager, DC Manager or another authorized management associate. Each day, all Inventory Adjustment Forms for controlled substances must be matched to the Daily Controlled Drug Transaction Report, and those for listed chemicals must be matched to the Listed Chemical Daily Activity Report. This information must be kept on file for the current year and the two previous years for impromptu audit inspections.

***21 CFR 205.50(b)(iii)(3)*** *All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.*

Access to computer on-hand adjustment capability should not be given to associates who have unsupervised access to controlled substances, i.e., the Compliance Coordinator, cage/vault clerks, etc.

Any associate having access to the adjustment program for controlled substances, or any other computer programs affecting the accountability of controlled substances, is to be considered "compliance critical" and undergo an initial criminal background records check upon gaining access, and undergo an annual criminal records check thereafter.

Associates granted access to the inventory adjustment program are not to leave their terminals at any time while "signed on" or working in the adjustment program; nor are they to enter their access authorization code on the keyboard in the presence of others who may possibility view the code. For further information on ABC's Password Protection Policy refer to Policy no. HR-5.2 in the AmerisourceBergen Associate Handbook.

A printout of all adjustments made to controlled substances must be reviewed by the Compliance Coordinator, DCM or Operations Manager. Adjustments **must not** be made to controlled substances without approval of a DC management official.

A management associate must review the Credit Memo Register daily and the DC Manager must approve all credits in excess of $5,000. In addition, a management associate must review all daily inventory adjustment activity.

## SECTION 10

### ARCOS
### ("Automation of Reports and Consolidated Orders System")

DEA differentiates between controlled substances for regulatory purposes; i.e., Schedule 2, 2N, 3, 3N, 4, and 5 controlled substances.

ARCOS items are all Schedule 2 and 2N controlled substances and Schedule 3 controlled substances that contain higher amounts of opium or coca leaves, their alkaloids and derivatives of alkaloids, as well as synthetic equivalents of both products.

***21 CFR 1304.04(d)*** *ARCOS participants who desire authorization to report from other than their registered locations must obtain a separate central reporting identifier. Requests for central reporting identifiers will be submitted to: ARCOS Unit, P.O. Box 28293, Central Station, Washington, DC 20005.*

ARCOS reports must be submitted to DEA's ARCOS Unit, Washington, DC, either on a monthly or quarterly basis. AmerisourceBergen has received permission from DEA to file monthly from the corporate offices. A copy of the letter from DEA authorizing the DC to submit their ARCOS reports from a central location must be maintained in file at the DC.

Each ARCOS report must be submitted by the fifteenth of the month following the period covered. All ARCOS maintenance must be completed by the tenth day of the month in order to submit the report by the fifteenth. A copy of the delivery receipt must be attached to the file copy of this report to indicate receipt by DEA.

These ARCOS reports are used by the Drug Enforcement Administration to ensure that no diversion takes place within the legitimate drug channels and to determine or "target" registrants who sell or distribute high volumes of these products. The ARCOS report data is also used to establish annual production quotas for these controlled substances and to develop estimated amounts of these products required for actual medical and scientific needs.

In addition, the ARCOS report information is used by the Drug Enforcement Administration to obtain and provide information to the United Nations worldwide drug control agencies as part of international treaty agreements and obligations in which the United States is involved.

The actual accomplishment of the ARCOS reporting requirements are usually assigned to an associate within each company and is compiled from computer files of controlled substance transactions. ARCOS reporting to the Drug Enforcement Administration is accomplished by preparation of controlled substance transaction information at the DC

These reports are submitted on computer media.

ARCOS "Daily Transaction Processing Reports" (Error Listings) received from the ARCOS Unit must be corrected and resubmitted to ARCOS **within thirty days of receipt.**

On a day-to-day operating basis, most associates involved in controlled substances handling or record keeping won't become involved in the preparation or review of ARCOS information or reporting.

It is very important that each controlled substance transaction be properly and accurately documented and entered into the computer files so that an accurate ARCOS report is sent from our company to DEA, Washington, D.C. Any errors, inaccurate transactions or records may result in unnecessary and time consuming corrections to the ARCOS report by the ARCOS Clerk. **Your personal attention and commitment to accuracy is extremely important** in ARCOS reporting and for maintaining accurate records and files as required by federal regulations.

## SECTION 11

## HIRING/SCREENING PROCEDURES

### A. GENERAL

DCs must adhere to the AmerisourceBergen screening process for all individuals working at the DC, including temporary workers.

As is the case with any major corporation, the testing and screening procedures utilized by AmerisourceBergen are designed to ensure that we hire the best applicants available. Hiring prospective associates in vault and cage areas, or associates having access to controlled substances, requires increased attention and caution when reviewing background and criminal record information.

### B. DEA RECORD CHECKS

***21 CFR 1301.76(a):*** *The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.* (The only method to determine if this has occurred is to conduct a DEA records check.)

DEA record checks for "compliance critical" associates must be conducted prior to granting access to controlled substances, but **should not** be conducted annually thereafter.

### C. EMPLOYEE SCREENING QUESTIONS

***21 CFR 1301.90 Employee screening procedures***
*It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to the overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is therefore, assumed that the following questions will become part of an employer's comprehensive employee screening program:*

*Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, date and sentence.*

*Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.*

*Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right to privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.*

The questions contained in **21 CFR 1301.90 Employee Screening Procedures:** are contained in the "AmerisourceBergen Application for Employment. The completed application must remain in the applicant or associate's personal file.

## D. APPLICANT WAIVER/CRIMINAL INFORMATION RELEASE FORM

A signed **Criminal Information Release/Waiver, CSRA Form #10** must be present for all associates. The **original** of the waiver form is to be maintained in the associate personnel file at all times and only copies of this authorization form mailed for criminal record inquiries.

## E. EMPLOYEE NOTIFICATION OF RESPONSIBILITIES

***21 CFR 1301.91 Employee Responsibility to report drug diversion***
*Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.*

***21 CFR 1301.92 Illicit activities by employees***
*It is the position of DEA that employees who posses, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall immediately become the subject of independent action regarding their continued employment. The employer will asses the seriousness of the employee's violation, the position of responsibility held by the employee, past record of*

*employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.*

21 CFR regulations (1301.91 and 1301.92) are printed on **CSRA Form #15, "Employee Notification of Responsibilities - 21 CFR 1301.91 & 1301.92"** which is to be prominently displayed on the associate bulletin board of each DC. In addition, **CSRA Form #16** lists these responsibilities with an associate certification paragraph, which must be signed by each new hire to the company and placed in their personnel file.

The DC must immediately initiate an evaluation regarding continued employment of any associate who is known to possess, sell, use, or divert controlled substances. Further, that immediately upon discovering this information, the CSRA Department is to be advised of such incident.

## F. CRIMINAL RECORD CHECKS

Criminal record inquiries must be made at **each** local law enforcement agency having jurisdiction in **each** city or locality of associate residence during the previous **five** years.

**Criminal record inquiries must be updated annually** on all associates having a continuing or ongoing authorization to access controlled substances. Inquiries must be made at the local law enforcement agency having jurisdiction in the associate's city of residence, the county law enforcement agency and/or the state criminal records agency.

## G. ASSOCIATE FILE REQUIREMENTS

- Completed and signed Employment Application
- Completed Consent/Waiver Form (Criminal Info Release)
- Criminal screen (Justifacts) within one year for compliance critical associates.
- DEA Record Check for compliance critical associates
- Drug Test Results (inception date Feb. 1995) maintained in separate file
- Signed Associate Notification of Responsibilities – 21 CFR 1301.91 & 1301.92
- Signed “compliance critical” job description for compliance critical associates

## SECTION 12

## THEFT AND LOSS POLICY

### A. CORPORATE THEFT POLICY

It is AmerisourceBergen Corporation policy that theft of any kind or in any degree will be not condoned in our company. Theft will be dealt with quickly and will result in prosecution of the individual(s) involved.

Our company makes every attempt to provide a safe, secure and honest working environment for all associates. This is what our associates deserve. We ask your assistance in immediately advising management if you observe any irregularities or suspect that company product is being diverted. All such reports should be directed to the Distribution Center Manager, Human Resources, Corporate Security and Regulatory Compliance or your Compliance Coordinator. Any information you relate to company management will be held in strict confidence.

### B. ASSOCIATE RESPONSIBILITY TO REPORT DIVERSION

As an associate of a registered distributor of controlled substances, each associate has a responsibility by federal administrative law (21 CFR 1301.91) to report any diversion of any controlled substance from our company by fellow associates. Associates should report all such activity to their supervisor or if the matter involves their supervisor, then the associate should report to Corporate Security and Regulatory Affairs, DCM and/or their Compliance Coordinator. Again, such information will be considered strictly confidential.

### C. NETWORK PROGRAM

AmerisourceBergen is a member of the "NETWORK PROGRAM". This is a mode of communication where associates can confidentially contact an objective representative of the company by way of a toll free number to discuss their individual security/safety concerns and ideas. The NETWORK Number is 1-800-241-5689.

Associate dishonesty hurts everyone, including honest hard working associates. Theft can definitely make a division less profitable, which in turn makes the division less able to compete. Businesses that are less competitive find it more difficult to reward associates and deliver quality service to their customers in these tough economic times. Now more than ever, our industry has become very competitive and we must maintain the high level of quality that our customers have come to expect. A common denominator among dishonest associates is that they rarely consider the impact of their actions on their fellow co-workers. Associate theft usually negatively impacts

associates morale, which generally affects the overall quality of the operation. Everyone pays the price for dishonesty.

Our experience has shown that frequently when an associate commits a dishonest act in the workplace, other associates have some knowledge concerning what took place. However, we recognize that when an associate has knowledge of dishonest or unethical behavior by another, it may be difficult for that associate to come forward to report the behavior to a supervisor. The associate may have a legitimate concern about reprisal, or retribution by co-associates. Reprisal and retribution will not be tolerated. As stated above it is the position of the DEA as outlined in Title 21 of the Code of Federal Regulations, section 1301.91, "that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer."

AmerisourceBergen recognizes the burden that an associate must deal with when confronting dishonest or unethical behavior in the workplace. Therefore, the more options made available to associates to report this kind of behavior, the better chance that the dishonest and unethical behavior will be reported and ultimately eliminated. Thus the development of the confidential toll free Network line for all associates to use.

## D. CONTROLLED SUBSTANCE THEFT OR LOSS (DEA FORM 106)

***21 CFR 1301.76(b)*** *The registrant shall notify the Field Office of the Administration in his area of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft.*

### 1. Notify DEA and Local Police

**Immediately upon discovery** of a theft or **significant loss** of controlled substances, the Distribution Center, as required by regulation, must **contact the nearest DEA Diversion Field Office by telephone, facsimile or by a brief written message explaining the circumstances.** A **Government Contact Form** must be completed to document the details of the conversation. The DC should also notify the local police as may be required by state law. **If there is a question as to whether a theft has occurred or a loss is significant, the DC should err on the side of caution and report it to DEA.**

**NOTE: The Corporate Security and Regulatory Affairs department must be notified prior to reporting any theft or loss to DEA.**

### 2. Complete DEA Form 106

**The DC shall also complete DEA Form 106** (Report of Theft or Loss of Controlled Substances). The DEA Form 106 will formally document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved, once this information has been determined conclusively.

**DEA Form 106**, along with a cover letter explaining the circumstances of the theft or loss, must be prepared. Two (2) copies of DEA Form 106 (the original and one copy) must be forwarded to DEA via traceable means with the delivery receipt attached to the company file copy. A copy of DEA Form 106 or applicable state form must be forwarded to all applicable state agencies if required.

In addition, a copy of the DEA Contact Form, DEA Form 106 and cover letter are to be forwarded to the Corporate Security and Regulatory Affairs Department. A copy of the DEA Contact Log must be attached to the file copy of the completed DEA Form 106 with any related documents and placed in file at the DC for a period of three years.

### 3. If Investigation Finds No Theft or Loss

If after an investigation of the circumstances surrounding the theft or significant loss it is determined that no such theft or significant loss occurred, no DEA Form 106 need be filed. However, the DC should notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

### 4. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. A significant loss depends, in large part, on the business of the registrant and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or distributor.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, a problem which must be reported to DEA, even though the individual amounts of missing controlled substances are not, in themselves significant. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

Some factors to consider for determining significant loss include:

- The schedule of the missing items.
- The abuse potential of the missing items.
- The abuse potential in your area of the missing items.
- The quantity missing.

- Is this the first time this loss has occurred? Has a similar loss occurred before?
- Was the loss reported to local law enforcement authorities?
- If there is a question as to whether a loss is significant, a registrant should err on the side of caution and report it to DEA.

If it is determined that the loss is **not significant**, place a record of the occurrence in your theft and loss file for future reference.

**In-Transit Loss**

When all or part of a shipment disappears, or never reaches its intended destination, the **supplier** is responsible for reporting the in-transit loss of controlled substances to DEA. A registrant is responsible for reporting any loss of controlled substances after a registrant has signed for or taken custody of a shipment. If it's discovered after that point that an in-transit loss or theft has occurred, the registrant must submit a DEA Form 106.

## E. REPORTING REQUIREMENTS FOR PRESCRIPTION DRUGS

Under the Prescription Drug Marketing Act (PDMA), state agencies have regulations which require registrants to submit a notice or report of theft or loss to the state whenever a loss of any prescription drug or device occurs. Upon discovery of any loss, theft, or non-reconcilable inventory discrepancy of a prescription drug or device, contact the Corporate Security and Regulatory Affairs department immediately for assistance. In instances requiring state regulatory agency notification, the Corporate Security and Regulatory Affairs department will advise accordingly. When notification of a prescription drug loss is made to a state regulatory agency, DCs are required to maintain a copy of the submitted notification for no less than three years.

## F. REPORTING REQUIREMENTS FOR LISTED CHEMICALS

***21 CFR 1310.05(a)(3)*** *Any unusual or excessive loss or disappearance of a listed chemical under control of the regulated person. The regulated person responsible for reporting a loss in-transit is the supplier.*

The Code of Federal Regulations mandates that any unusual or excessive loss of a listed chemical shall be reported to the Special Agent in Charge of the DEA Diversion Office in the registrant's local area. This notification should be by telephone and then followed with a written report within 15 days of notification. A **Listed Chemical Incident Report, CSRA Form #22** must be used for this notification.
Losses should also be immediately reported to the Corporate Security and Regulatory Affairs department.

## SECTION 13

## ADDITIONAL PDMA REQUIREMENTS

### A. HOUSEKEEPING

***21 CFR 205.50(a)*** *All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:*

*(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;*
*(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;*
*(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;*
*(4) Be maintained in clean and orderly condition; and*
*(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.*

Distribution Center housekeeping procedures must be sufficient to provide a clean floor and dust free storage of pharmaceutical product.

The warehouse must be free of infestation by rodents, insects, vermin, etc., and an exterminator must regularly inspect the Distribution Center.

Adequate shelving space shall be maintained at all times, for both saleable and non-salable products, to prevent intermixing of items and improper order filling. Adequate backstock shelving will be maintained to accommodate normal quantities of backstock product. Should inadequate space become a problem, measures will be taken to increase shelving capacity within the DC.

### B. STOCK ROTATION

***21 CFR 205.50(g)(1)*** *…Wholesale drug distributors shall include in their written policies and procedures…A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.*

Stock rotation procedures must be accomplished and documented.

**Stock Rotation Procedures:**

The purpose of this policy is to define the systems and procedures used to ensure the products being distributed are not beyond their expiration date and that the oldest product (product with the least amount of dating left before the expiration date) is shipped out first.

**Exceptions:**

This policy defines the normal procedures to be followed. Temporary deviations are allowed but are not encouraged. An example of such a deviation would be if an account ordered a large quantity of a product and desires it all to be of the same lot number. In order to comply with this request, "older" products may have to be skipped over. When restocking returns, the return may have a later expiration than the product on the shelf and would be placed on the front of the shelf rather than behind the present product.

**Stock Rotation Procedures To Be Followed:**

a. Receiving department personnel are to spot check product to insure incoming product is received within the expiration date, and is not "short-dated."

b. Proper stock rotation is the responsibility of each stock clerk and is a specific job requirement of all personnel performing restocking activities.

c. When the stock is moved to the open or back stock location the following is to take place:
   i. *Bulk Stock:* Incoming product should be stored ***behind*** the product on the rack or shelf, or ***below*** another pallet of the same product.
   ii. *Shelf Stock:* Replenishment product will be placed behind the existing stock on the shelf.
   iii. *Flow Racks:* Generally ensure stock rotation and that product is not restocked from the front. The date on the "oldest" stock in the flow rack should be checked before adding new product.

It is the responsibility of each stock clerk to check the expiration date on existing stock and incoming stock to ensure that oldest stock is properly stocked to sell the oldest product first.

*Returned Product:* Special attention will be required in the replenishment of returned product since this product will generally have a shorter expiration date than most of the product in stock. In most, but not all cases, it will be necessary to place returned product in front of existing stock. Returned products involving large quantities of the

same product will require the stock clerk to check each item to ensure proper placement on the shelves according to expiration date.

Supervisors performing their normal duties will observe stock clerks and insure stock rotation procedures are consistently being followed by:

- Spot checking product on flow racks, static shelves, bulk stock tables, and pallet racks for proper placement of stock in accordance with this stock rotation policy.
- Allocating specific times during each week for associates to check stock in their areas and remove "short-dated" items.
- Ensure that all stock is checked for expiration dates prior to physical inventories.

Returns Personnel Responsibilities:

(1) Will ensure that no product or product with short dating is approved for restocking in any warehouse location.

(2) An exception may be required if a particular manufacturer has requested that product with a shorter than normal expiration date continue to be shipped (e.g., Abbott Hospital DC injectables).

Order Filler and Stock Clerk Product Rotation Responsibilities:

(1) Order fillers/clerks as part of their job responsibilities are to randomly spot check throughout their shift to ensure product is not shipped that is outdated, or "short-dated."

(2) Order fillers/clerks must be especially alert to assure no outdated product is shipped from the DC.

Inventory Control Personnel Stock Rotation Responsibilities:

(1) Inventory personnel will check product during special counts, cycle counts, or other inventories for proper stock rotation placement of product.

(2) Inventory personnel will verify stock rotation policies have been accomplished when preparing product for inventory, when relocating stock, consolidating locations, etc.

(3) Inventory personnel will work with and notify the warehouse supervisors of any stock placement problems observed and inadequate accomplishment or failure to accomplish stock

rotation procedures by individuals or in specific areas of the company.

Controlled Substance Stock Rotation:

(1) All stock rotation procedures are the responsibility of the controlled substance clerks working in the cage or vault areas.

(2) The procedures listed above in this section of the manual also apply to all controlled substance items whether in the cage or vault areas.

## C. HUMIDITY/TEMPERATURE MONITORING

***21 CFR 205.50[c]*** *All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).*

*(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.*

*(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.*

The Distribution Center's refrigeration unit(s) must be equipped with the following:

- Temperature indicator and control device with the temperature documented at least once per day.
- Monitored by Alarm Company for severe temperature fluctuation.

The Distribution Center must utilize a humidity/temperature-monitoring device in the warehouse with the records of the recordings maintained in file for the prescribed period of time depending on the state.

## D. PRODUCT RECALL PROCEDURES

**Introduction**

Title 21 of the Code of Federal Regulations, Part 7 provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. These guidelines make it clear that FDA expects these manufacturers and distributors to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful. Under the guidelines, manufacturers and distributors are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls, and to undertake recalls when asked to do so by the FDA.

Manufacturers and distributors are responsible to develop contingency plans for product recalls that can be put into effect, if and when needed. FDA's role under the guidelines is to monitor recalls and assess the adequacy of the manufacturers or distributors action. After a recall is completed, FDA will verify that the product is destroyed or suitably reconditioned and will investigate why the product or packaging was defective/insufficient in the first instance.

The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

**Class I** recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinal toxin, food with undeclared allergens, a label mix-up on a life saving drug, or a defective artificial heart valve.

**Class II** recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is under-strength but that is not used to treat life-threatening situations.

**Class III** recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); off-taste, color, or leaks in a bottled drink, and lack of English labeling in a retail food.

FDA develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that each defective product has been recalled or reconditioned. In contrast, for a Class III recall, the FDA may decide that it only needs to spot check to make sure the product is off the market. Even though the manufacturer or distributor recalling the product may issue a press release, FDA seeks publicity about a recall only when it believes the public needs to be alerted about a serious hazard.

There are three "depths" of recalls, which depend on the products degree of hazard and the extent of distribution.

***Consumer or User Level:***
This may vary with product, including any intermediate wholesale or retail level. A consumer or user may include the individual consumer, including a patient, physician, restaurant, hospital, etc.

***Retail Level:***
Recall is necessary to the level immediately preceding the consumer or user level. This includes retail groceries, pharmacies, hospital pharmacies, dispensing physicians, institutions such as clinics or nursing homes, and any intermediate levels of distribution.

***Wholesale Level:***
All distribution levels between the manufacturer and the retail level. This level may not be encountered in every recall situation, i.e., the manufacturer may sell directly to the retailer.

**Recall Policy**

The following policy applies to all federal, state, or locally mandated drug or product recalls, and any manufacturer initiated recall actions.

**NOTE: Each Distribution Center and Supply Chain Services must maintain a file of all communications pertaining to any recall. The file can be a combination of paper and electronic documents. Each Distribution Center must have a person(s) designated as a recall contact. Recall records must be maintained for a period of three years from the date the recall is initiated by the manufacturer or distributor.**

A. Policy:

1. Supply Chain Services Responsibilities:

a. Works with manufacturer or distributor that initiated the recall to validate the Class and Level of the recall.
b. Notifies Distribution Centers of Recalls. Customer Listings and copies all Customer communications are sent to Distribution Centers.
c. Tracks recall notifications
d. Creates Customer Listings for Retail or Consumer Level Recalls
e. Ensures Retail Level notifications are sent to Retail level Customers
f. Invoices manufacturers for Recall Notifications
g. Maintains records for at least three years.

h. Integrates this Procedure into the Recall Toolkit.

2. DCM Responsibilities:

a. Ensures that the Distribution Center implements and accomplishes the following recall procedures:
b. Product is immediately removed from all shelf locations for open stock and back stock. This product is immediately taken to the Returns Department for segregation and quarantine
c. Affix a "Shelf Reference Card" to the shelf location, if applicable, to ensure that shipments from the manufacturer and returned goods do not get restocked on the shelf or placed into the back stock location
d. Deduct the product quantities from saleable inventory
e. Maintain a file on each recalled item(s). File contains paper and/or electronic documents that track recalled product movement and any customer notifications from the time the recall is initiated.
f. Send copies of the recall, with amounts found, date checked and the clerk's initials, to the Distribution Center Returns Department and to the individual at the Distribution Center responsible for recall record keeping
g. Respond to information requested by organization initiating the recall even if no product was received at the Distribution Center. Typically response is made via preprinted postcard or letter provided by the organization issuing the recall.
h. Invoice manufacturer for returned and/or destroyed inventory, handling costs and freight costs using HDMA guidelines.
i. Complies with instructions provided by the organization issuing the Recall.
j. Complies with instructions provided by Supply Chain Services
k. Maintains records for at least three years

3. CSRA Responsibilities:

a. Involved in potential counterfeit product recalls

B. Actions Considerations for Depth of Recall

1. Consumer Or User Level Recall:

a. Supply Chain Services Responsibilities:

1. Contact the manufacturer, if necessary, to determine

the lot number, time frame, products or other information pertaining to the recall.

2. Determine the time frame of the recall as it applies to AmerisourceBergen and determine how much product was shipped from AmerisourceBergen to Customers.

3. Obtain a printout of all Customers who purchased the product during the designated time period and sent listing via email to all Distribution Centers.

4. Prepare the master drug recall letter.

   a) Send the letter via US mail to each customer. The letter, outside mailing envelope and return envelope must be stamped or annotated " URGENT DRUG RECALL. Attn: Pharmacy"

   b) Send the letter via email to all Distribution Centers.

5. Provide recall letter, either paper or electronic, to all Regional Sales Administrators and National Account Leaders for distribution to all Account Managers. The letter must contain at least the manufacturer information regarding the recall.

b. DCM Responsibilities

1. Contact data processing to complete the necessary activities to put the recall information in the "message field" of the company invoices for the next five days. Where multiple recalls are in effect at the same time, the notices will be placed in the order received. Class I Recall notices will always be immediately placed on the invoice. Message content should be minimal with supplier name and product number just to make Customers aware of a current recall.

2. If requested by Supply Chain Services, include the recall letter in totes with orders to customers

3. Notify the Customer Service Department or Compliance Department of the recall. Any replies or responses to the telephone calls made by DC personnel must be

recorded on the appropriate recall record or annotated on a prepared computer printout response record.

4. Notify Returns Department personnel of the recall. Assign individual(s) to process recalled items. The individual(s) must accurately record and know which customers have returned product and in what quantities. The individual(s) must be provided with a copy of all letters mailed by the company and received from the manufacturer regarding the recall.

5. All recalled product must be recorded on the appropriate recall record or annotated on a prepared computer printout response record.

6. If Recall Product is shipped from a Distribution Center that is not the primary servicing Distribution Center, the Recalled product is returned to the primary Distribution Center.

7. The Distribution Center with primary responsibility for a Customer is responsible for notifying the Customer by placing a copy of the Recall letter with that Customer's next shipment.

2. Retail Level Recall:

a. Supply Chain Services Responsibilities
1. Same as Consumer Level Recall

b. Distribution Center Responsibilities
1. Same as Consumer Level Recall.

3. Wholesale Level Recall:

a. Follow the procedures listed under II. A. Policy. No additional action in necessary for a wholesale level recall.

C. Additional Action Considerations for Class I Recall

1. Supply Chain Services Responsibilities
a. No Additional actions

2. DCM Responsibilities:

a. Include a copy of the AmerisourceBergen recall letter manufacturer's notice and response forming the totes of all customers on the customer listing provided by Supply Chain Services. DCM may decide to notify all customers via totes base on operational efficiencies.

D. Segregation of Recalled Product:

The segregation and quarantine of all recalled products is an important mandated requirement. All products and items returned from customers or from any other source must be promptly taken to the Returns Department to ensure they do not inadvertently re-enter saleable inventory or the distribution channels.

## SECTION 14

## COMPLIANCE TRAINING

### A. AMERISOURCEBERGEN COMPLIANCE TRAINING PROGRAM

AmerisourceBergen requires each person involved in the handling or record keeping of controlled substances to attend AmerisourceBergen Corporation's **"Regulatory Compliance Training Program."**

This is approximately six (6) hours of intensive training in 21 CFR regulations (Title 21 Code of Federal Regulations) which covers DEA and PDMA requirements for licensed/registered distributors of controlled substances, listed chemicals and prescription drugs. In addition, policy, methods and recommendations are made regarding daily activities in the handling and record keeping of controlled substances, listed chemicals and prescription drugs that may improve our voluntary compliance efforts. Specific State requirements must also be covered in this training.

These training sessions are normally presented at the distribution center; however, they may be presented at the annual Compliance Conference, or at AmerisourceBergen corporate headquarters. A certificate of attendance is presented to each associate completing the program. **CSRA Form #4, Compliance Training Attendance List** should be used to document attendance to this training.

Annual update training is required for all "Compliance Critical" associates. However, six hours of training is not required for annual update training.

Each associate involved in the handling or record keeping of controlled substances, listed chemicals and prescription drugs must fully understand his/her responsibility for accurate performance and for ensuring that proper procedures are followed. The Compliance Coordinator or another Supervisor who covers specific job responsibilities and requirements will give instruction.

### B. PDMA/LISTED CHEMICAL TRAINING

AmerisourceBergen requires each person involved in the handling or record keeping of prescription drugs and/or listed chemical products to attend AmerisourceBergen Corporation's **"PDMA/Listed Chemical Training Program."**

This is approximately two (2) hours of intensive training in 21 CFR regulations which covers DEA and PDMA requirements for licensed/registered distributors of listed chemicals and prescription drugs. In addition, policy, methods and recommendations are made regarding daily activities in the handling and record keeping of listed

chemicals and prescription drugs that may improve our voluntary compliance efforts. Specific State requirements must also be covered in this training.

Each associate involved in the handling or record keeping of listed chemicals and prescription drugs must fully understand his/her responsibility for accurate performance and for ensuring that proper procedures are followed. The Compliance Coordinator or another Supervisor who covers specific job responsibilities and requirements will give instruction.

## C. DRIVER TRAINING

Each AmerisourceBergen delivery driver must complete training in **"Delivery Policies & Procedures", CSRA Form #26**.

## SECTION 15

## COMPLIANCE AUDITS

### A. AUDIT PROTOCOL

Each Distribution Center Manager (DCM) must maintain **in writing** a list of those associates within the company who would assume responsibility and control of any DEA, FDA or other regulatory agency inspections in the event of manager's absence. The individual or individuals assigned this responsibility are to have a complete knowledge and understanding of compliance requirements, the DC's compliance procedures, and the location of documents and printouts necessary to conduct a compliance audit.

Each DC must have in their possession and be familiar with a **"Government Agency Inspection Guidelines & Checklist", CSRA Form #1** for use in conducting Government compliance audits/inspections. Completion of CSRA Form #1 is not required for CSRA audits.

**Note: A copy of CSRA Form #1 must be forwarded to CSRA within 30 days of the conclusion of a DEA compliance audit.**

Each DC manager and/or Compliance Coordinator must maintain liaison with the DEA Diversion Group Supervisor or the Diversion Investigator responsible for the DC's compliance enforcement.

### B. DISTRIBUTION CENTER SELF AUDITS

Internal Compliance Audits must be conducted by DC associates to determine accuracy of controlled substance transactions and record keeping. Local management or compliance associates must conduct these audits semiannually with documentation maintained on file at the DC until the next CSRA audit.

### C. CORPORATE AUDITS

AmerisourceBergen maintains a Compliance Audit Program to monitor compliance activities for effectiveness. These audits are conducted at the discretion of the CSRA department without prior notice to DC management. The DC could reasonably expect such a corporate compliance audit to take place at least once annually.

These audits will include an accountability audit of at least eight (8) controlled substance products. Printouts provided for the accountability audit must be sufficient to produce balanced and acceptable results without rerunning the printouts.

## D. DRUG ENFORCEMENT ADMINISTRATION AUDITS

The Drug Enforcement Administration has the legal responsibility and authority to inspect our DEA registered locations to determine the effectiveness of our compliance efforts at any time. The regulations state that a distributor shall be inspected as circumstances may require, based in part on the registrant's history of compliance and maintenance of effective controls and procedures to guard against diversion of controlled substances.

## E. STATE INSPECTIONS

State Licensing Agencies have the legal responsibility and authority to inspect our licensed locations to determine the effectiveness of our compliance efforts with state statutes and regulations. The frequency of these inspections may vary from state to state.

## SECTION 16

## CORPORATE SECURITY & REGULATORY AFFAIRS FORMS INDEX

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| CSRA Form 11 (a) | Authorized Access List Form |
| CSRA Form 11 (b) | Restricted Area Notice for Posting |
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CSRA Form 20 Product Return to Customer Form

CSRA Form 21 Regulated Chemical Transaction Report

CSRA Form 22 Listed Chemical Incident Report

CSRA Form 24 Inventory Adjustment Form

CSRA Form 25 Guidelines, Policy & Procedures Manual for Common Carriers

CSRA Form 25 (a) ABC Carrier Service Agreement

CSRA Form 26 Delivery Policies & Procedures

CSRA Form 27 Narcotic Treatment Program Authorized Signature Form

CSRA Form 28 Duress Code Instruction

CSRA Form 29 Robbery & Violence Prevention Form

CSRA Form 30 (a) Violence Prevention Procedures

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CSRA Form 31 Agreement for Donation of Product

CSRA Form 32 DEA Order Form Guidelines

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CSRA Form 34 Customer Notification of Order Form Regulations

CSRA Form 35 Customer Notification of DEA Registration Modification Procedures

CSRA Form 36 Restricted Area Posting

CSRA Form 37 Carrying Personal Packages Posting

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